December 1995
Volume 40, Number 12
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# RESPIRATORY CARE

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# Insight

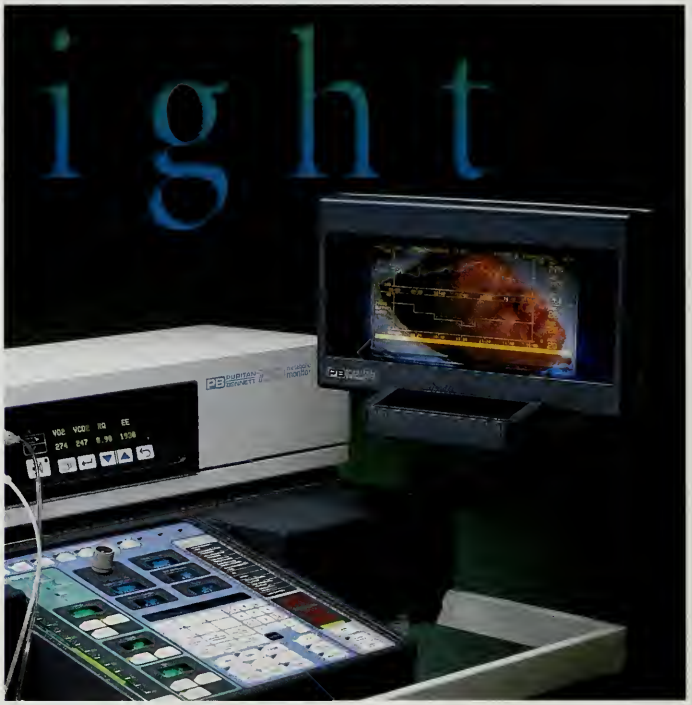
apprehending

the inner nature

of things

or of

seeing intuitively.



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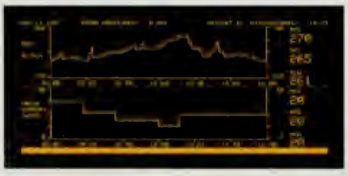

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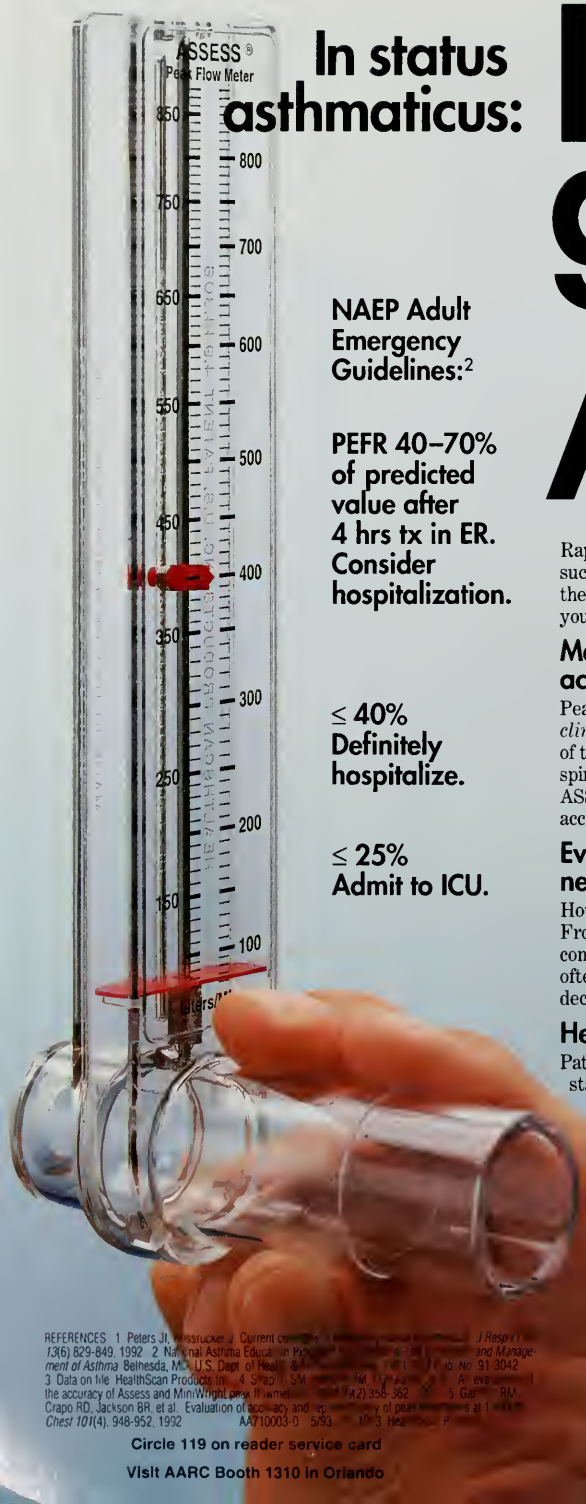


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**Editorials, Commentaries, and Reviews To Note**

**Smoking and Health: Physician Responsibility A Statement of the Joint Committee on Smoking and Health** (special report)—American College of Chest Physicians; American Thoracic Society; Asia Pacific Society of Respirology; Canadian Thoracic Society; European Respiratory Society; and International Union Against Tuberculosis and Lung Disease. Chest 1995;108(4):1118-1121.

**Assessment of Asthma in the Workplace** (statement)—Chair: M Chan-Yeung. Chest 1995;108(4):1084-1117.

**The Challenge of Tuberculosis: Statements on Global Control and Prevention** (statement)—DA Enarson, J Grosset, A Mwinga, ES Hershfield, R O'Brien, S Cole, L Reichman, and finalized by conference participants, Washington DC, Sept 14-15, 1995. Lancet 1995;346:809.

**Towards the Elimination of Tuberculosis** (editorial)—R Horton. Lancet 1995;346:790.

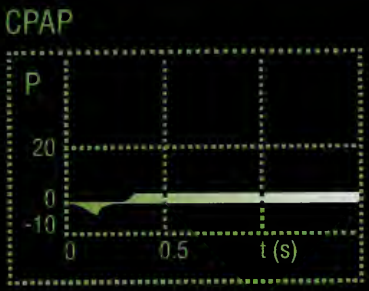
**Standardization of Spirometry, 1994 Update** (statement)—The American Thoracic Society Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. Am J Respir Crit Care 1995;152:1107-1136.

**Continuing Patient Care with Metered-Dose Inhalers**—A Woodcock. J Aerosol Med 1995;8 (Suppl 2):S-5.

International guidelines recommend inhaled therapy over oral therapy for asthma because of greater efficacy and safety. Metered-dose inhalers (MDIs) are the delivery system of choice for the majority of patients with asthma. They have been well tried and tested and proven to be safe, reliably delivering a reproducible and precise dose, and account for 85% of the 400 million inhalers currently sold worldwide. Current products using chlorofluorocarbon (CFC) 11/12 as the propellant are being reformulated. Under the Montreal Protocol, CFCs are to be phased out worldwide, though MDIs have been granted temporary exemption, thus far until 1997. Two propellants, hydrofluoroalkane (HFA) 134a and 227, have been identified by the pharmaceutical industry to replace CFCs. However, they have different properties and reformulation has been difficult in relation to surfactants, valves and elastomeric seals. The manufacturing process has been re-engineered to take place at high pressure, because at normal pressure HFA 134a is a gas, in contrast with CFC 11 which is a liquid at room temperature. Glaxo has carried out an extensive toxicological assessment of HFA 134a and thorough clinical testing has shown it to be well tolerated. To date they have carried out safety and efficacy testing on reformulations of salbutamol, salmeterol, and fluticasone propionate (FP). Single-dose studies of salbutamol, 200 $\mu$g, with HFA 134a have been shown to provide equivalent protection against bronchial provocation by histamine in both adults and children with asthma when compared with the currently available CFC preparations. In a subsequent 4-week study, both formulations had similar effects on morning peak flow and the patients believed that the 2 preparations were equivalent. Single doses of salmeterol, 50 $\mu$g and 100 $\mu$g, provide equal protection against bronchial provocation by methacholine compared with the respective dose of the current CFC formulation. A 4-week study comparing both preparations showed equivalent effect with similar improvements in morning peak flow for both preparations. A double-blind study has compared FP, 250 $\mu$g twice daily, with HFA 134a and the current CFC formulation in moderate asthmatics previously taking up to 800 $\mu$g a day of inhaled corticosteroid. Morning peak flow improved by approximately 20 L/min in both treatment groups. Monitoring of adverse events and clinical and laboratory test data has shown a very similar profile for safety and tolerability of HFA 134a formulations when compared with current CFC formulations, with no new or unexpected adverse events in over 2,000 patients. Both propellants will be available during the transition period. Doctors and patients will continue to see the need for MDIs and they will remain the most widely used delivery system for asthma therapy into the next millennium.

**Ambient Air Pollution and Hospitalization for Congestive Heart Failure among Elderly People in Seven Large US Cities**—RD Morris, EN Naumova, RL Munasinghe. Am J Public Health 1995;85(10):1361.

OBJECTIVES: Preexisting data sets were used to investigate the association between hospital admissions for congestive heart failure and air pollutants. METHODS: Medicare hospital admissions data, ambient air pollution monitoring data, and meteorological data were used to create daily values of hospital admissions for congestive heart failure, maximum hourly temperature, and maximum hourly levels of carbon monoxide, nitrogen dioxide, sulfur dioxide, and ozone. Data were compiled for each of 7 cities (Chicago, Detroit, Houston, Los Angeles, Milwaukee, New York, and Philadelphia) for 1986 through 1989. Single-pollutant and multipollutant models with adjustments for temperature, seasonal effects, and weekly cycles were used in conducting negative binomial regression analyses. RESULTS: Ambient carbon monoxide levels were positively associated with hospital admissions for congestive heart failure in the single-pollutant and multipollutant models for each of the 7 cities. The relative risk of hospital admission for congestive heart failure associated with an increase of 10 ppm in carbon monoxide ranged from 1.10 in New York to 1.37 in Los Angeles. CONCLUSIONS: Hospital admissions for congestive heart failure ex-

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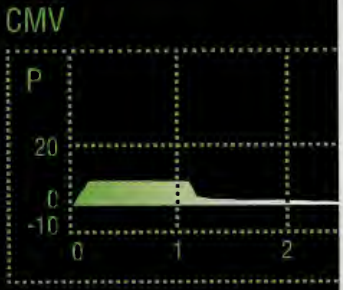


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hibited a consistent association with daily variations in ambient carbon monoxide. This association was independent of season, temperature, and other major gaseous pollutants.

**Multidrug-Resistant Tuberculosis in Patients without HIV Infection**—EE Telzak, K Sepkowitz, P Alpert, S Mannheimer, F Medard, W El-Sadr, S Blum, A Gagliardi, N Salomon, G Turett. N Engl J Med 1995;333(14):907.

BACKGROUND: Investigations of outbreaks of multidrug-resistant tuberculosis have found low rates of treatment response and very high mortality, and they have mainly involved patients with advanced human immunodeficiency virus (HIV) infection. For patients without HIV infection, 1 study reported an overall rate of response to treatment of 56%, and the mortality from tuberculosis was 22%. We investigated treatment response and mortality rates in 26 HIV-negative patients in New York with multidrug-resistant tuberculosis. METHODS: We obtained detailed data from 7 teaching hospitals in New York City on patients with multidrug-resistant tuberculosis—defined as tuberculosis resistant at least to isoniazid and rifampin—who were HIV-negative on serologic testing. Lengths of times from diagnosis to the initiation of appropriate therapy and from the initiation of appropriate therapy to conversion to negative cultures were assessed. Therapeutic responses were evaluated by both microbiologic and clinical criteria. RESULTS: Between March 1991 and September 1994, 26 HIV-negative patients were identified and treated. Of the 25 patients for whom adequate data were available for analysis, 24 (96%) had clinical responses; all 17 patients for whom data on microbiologic response were available had such a response. The median times from diagnosis to the initiation of appropriate therapy and from the initiation of therapy to culture conversion were 44 days (range, 0 to 181) and 69 days (range, 2 to 705), respectively. Side effects requiring the discontinuation of medication occurred in 4 of 23 patients (17%) who were treated with second-line antituberculosis medications. The median follow-up for the 23 patients who responded and who received appropriate therapy was 91 weeks (range, 41 to 225). CONCLUSIONS: In this report from New York City, HIV-negative patients with multidrug-resistant tuberculosis, contrary to previous reports, responded well to appropriate chemotherapy, both clinically and microbiologically.

**Physical Properties of Aerosolized Immunoglobulin for Inhalation Therapy**—PC Rimensberger, C Roth. J Aerosol Med 1995;8(3):255.

Animal studies suggest that passive immunization by intratracheal application of gammaglobulins may succeed in treating small children and infants with severe lower respiratory tract infection caused by respiratory syncytial virus (RSV). Since proteins foam easily when stirred up or used with compressed air, the feasibility of nebulization of the immunoglobulin solution (IVIG, Sandoglobulin®) had to be tested. The therapeutic effect of a drug delivered via inhalation is proportional to the mass of aerosol deposited in the lungs. For a fixed breathing pattern, the amount deposited per unit of time in the thoracic region depends on mass flowrate and distribution of aerosol mass by droplet size. Both these variables were determined in relation to the weight concentration (osmolality), viscosity, and surface tension of the IVIG solution for 4 compressed air nebulizers. The mass flowrate of the spray decreases as the weight concentration of the solution increases, but droplet size distribution does not change. If the IVIG solution does not exceed 5% and the airflow rate is 6 L/min, a mass flow of about 150 mg to 250 mg (7.5 to 12.5 mg IVIG) per minute is obtained, depending on the physical characteristics of the nebulizer used. Low mass median diameter of about 2 $\mu$m and a mass distribution with a high percentage of the droplets below 6 $\mu$m will allow optimum intrapulmonary deposition in infants.

**The Effectiveness of Vaccination against Influenza in Healthy, Working Adults**—KL Nichol, A Lind, KL Margolis, M Murdoch, R McFadden, M Hauge, S Magnan, M Drake. N Engl J Med 1995;333(14):889.

BACKGROUND: Although influenza causes substantial morbidity and mortality in all age groups, current recommendations emphasize annual immunization for people at high risk for complications of influenza. We conducted a double-blind, placebo-controlled trial of vaccination against influenza in healthy, working adults. METHODS: In the fall of 1994, we recruited working adults from 18 to 64 years of age from in and around the Minneapolis-St Paul area and randomly assigned them to receive either influenza vaccine or placebo injections. The primary study outcomes included upper respiratory illnesses, absenteeism from work because of upper respiratory illnesses, and visits to physicians' offices for upper respiratory illnesses. The economic benefits of vaccination were analyzed by estimating the direct and indirect costs associated with immunization and with upper respiratory illnesses. RESULTS: We enrolled a total of 849 subjects. Baseline characteristics were similar in the 2 groups. During the follow-up period, consisting of the 1994-1995 influenza season (December 1, 1994, through March 31, 1995), those who received the vaccine reported 25% fewer episodes of upper respiratory illness than those who received the placebo (105 vs 140 episodes/100 subjects, $p < 0.001$), 43% fewer days of sick leave from work due to upper respiratory illness (70 vs 122 days/100 subjects, $p = 0.001$), and 44% fewer visits to physicians' offices for upper respiratory illnesses (31 vs 55 visits/100 subjects, $p = 0.004$). The cost savings were estimated to be $46.85/person vaccinated. CONCLUSIONS: Vaccination against influenza has substantial health-related and economic benefits for healthy, working adults. *See the related editorial:* ***Influenza Vaccine for Healthy Adults?****—PA Patriarca, RA Strikas. N Engl J Med 1995;333(14):933-934.*

**Delivery and Retention of an Insulin Aerosol Produced by a New Jet Nebulizer**—J Jendle, BE Karlberg, J Persliden, L Franzén, M Arborelius Jr. J Aerosol Med 1995;8(3):243.

This study describes the delivery and distribution of an aerosol generated by a jet nebulizer (MAXIN®) in an experimental animal model. Anesthetized, intubated and ventilated piglets inhaled radiolabeled technetium diethylenetriaminepenta-acetic acid ($^{99m}$Tc-DTPA) through the endotracheal tube. The lungs were excised en bloc and scintigraphed, using a computerized gamma camera to evaluate the pattern of distribution. By nebulizing radiolabeled $^{125}$I-insulin and comparing the activity deposited on inspiratory and expiratory electrostatic filters, delivery and retention of nebulized insulin was assessed. The distribution of aerosol in the lungs was very even and reached the most peripheral parts. The delivery of nebulized insulin was calculated to be 88.9 ± 5.3% and 36.1 ± 8.8% of the insulin delivered to the respiratory tract was retained. The immediate local effects of insulin aerosol administration on the lungs were evaluated using light microscopy. No adverse effects were observed at histopathologic examination of the lung tissue. CONCLUSION: This study shows a high penetration of aerosol to the peripheral parts of the lung and efficient delivery of nebulized insulin when using the MAXIN-nebulizer.

**Bacterial Pneumonia in Persons Infected with the Human Immunodeficiency Virus**—RE Hirschtick, J Glassroth, MC Jordan, TC Wilcosky, JM Wallace, PA Kvale, N Markowitz, MJ Rosen, BT Mangura, PC Hopewell, the Pulmonary Complications of HIV Infection Study Group. N Engl J Med 1995;333(13):845.

BACKGROUND: Patients with human immunodeficiency virus (HIV) infection are at increased risk for bacterial pneumonia in addition to opportunistic infection. However, the risk factors for bacterial pneumonia and its incidence in this population are not well defined. METHODS: In a multicenter, prospective, observational study, we monitored 1,130 HIV-positive and 167 HIV-negative participating adults for up to 64 months for pulmonary disease. The HIV-positive group comprised 814 homosexual or bisexual men, 261 injection drug users, and 55 female partners of HIV-infected men. RESULTS: There were 237 episodes of bacterial pneumonia among the HIV-positive participants (rate, 5.5/100 person-years), as compared with 6 episodes among the HIV-negative participants (rate, 0.9/100 person-years; $p < 0.001$). The rate of bacterial pneumonia increased

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with decreasing CD4-lymphocyte counts (2.3, 6.8, and 10.8 episodes/100 person-years in the strata with more than 500, 200 to 500, and fewer than 200 cells/mm$^3$, respectively; $p \leq 0.022$ for each comparison). Injection-drug users had a higher rate of bacterial pneumonia than did homosexual or bisexual men or female partners. In the stratum with the fewest CD4 lymphocytes, cigarette smoking was associated with an increased rate of pneumonia. Mortality was almost 4 times higher among participants with an episode of pneumonia than among the others. Prophylaxis with trimethoprim-sulfamethoxazole was associated with a 67% reduction in confirmed episodes of bacterial pneumonia ($p = 0.007$). CONCLUSIONS: Bacterial pneumonia is more frequent in HIV-positive persons than in seronegative controls, and the risk is highest among those with CD4-lymphocyte counts below 200/mm$^3$ and among injection-drug users.

**Noninvasive Ventilation for Acute Exacerbations of Chronic Obstructive Pulmonary Disease**—L Brochard, J Mancebo, M Wysocki, F Lofaso, G Conti, A Rauss, G Simonneau, S Benito, A Gasparetto, F Lemaire, D Isabey, A Harf. N Engl J Med 1995;333(13):817.

BACKGROUND: In patients with acute exacerbations of chronic obstructive pulmonary disease, noninvasive ventilation may be used in an attempt to avoid endotracheal intubation and complications associated with mechanical ventilation. METHODS: We conducted a prospective, randomized study comparing noninvasive pressure-support ventilation delivered through a face mask with standard treatment in patients admitted to 5 intensive care units over a 15-month period. RESULTS: A total of 85 patients were recruited from a larger group of 275 patients with chronic obstructive pulmonary disease admitted to the intensive care units in the same period. A total of 42 were randomly assigned to standard therapy and 43 to noninvasive ventilation. The 2 groups had similar clinical characteristics on admission to the hospital. The use of noninvasive ventilation significantly reduced the need for endotracheal intubation (which was dictated by objective criteria): 11 of 43 patients (26%) in the noninvasive-ventilation group were intubated, as compared with 31 of 42 (74%) in the standard-treatment group ($p < 0.001$). In addition, the frequency of complications was significantly lower in the noninvasive-ventilation group (16% vs 48%, $p = 0.001$), and the mean (±SD) hospital stay was significantly shorter for patients receiving noninvasive ventilation (23 ± 17 days vs 35 ± 33 days, $p = 0.005$). The in-hospital mortality rate was also significantly reduced with noninvasive ventilation (4 of 43 patients, or 9%, in the noninvasive-ventilation group died in the hospital, as compared with 12 of 42, or 29%, in the standard-treatment group; $p = 0.02$). CONCLUSIONS: In selected patients with acute exacerbations of chronic obstructive pulmonary disease, noninvasive ventilation can reduce the need for endotracheal intubation, the length of the hospital stay, and the in-hospital mortality rate. *See the related editorial: **Noninvasive Ventilation in Chronic Obstructive Pulmonary Disease**—MW Elliott. N Engl J Med 1995;333(13):870-871.*

**Hyperbaric Oxygen Treatment for Haemorrhagic Radiation Cystitis**—RFM Bevers, DJ Bakker, KH Kurth. Lancet 1995;346:803.

Radiation-induced severe haemorrhagic cystitis is difficult to treat. Conventional treatments may decrease haematuria but do not affect the radiocystitis itself. Hyperbaric oxygen treatment has been reported to do both. We report the results of a prospective study of hyperbaric oxygen (20 sessions of 100% oxygen inhalation at 3 bar for 90 min in a multiplace hyperbaric chamber) to 40 patients with biopsy-proven radiation cystitis and severe haematuria. Haematuria disappeared completely or improved in 37 patients after treatment. Mean follow-up was 23.1 months (range 1-74); and the recurrence rate was 0.12/year. There were no adverse effects. Hyperbaric oxygen treatment should be considered for patients with severe radiation-induced haematuria.

**Are Asthma-Like Symptoms Due to Bronchial or Extrathoracic Airway Dysfunction?**—C Bucca, G Rolla, L Brussino, V De Rose, M Bugiani. Lancet 1995;346:791.

Patients with asthma-like symptoms may not have asthma but obstruction of the extrathoracic airway (EA). To evaluate if dysfunction of the EA causes asthma-like symptoms, we assessed bronchial and EA responsiveness to inhaled histamine in 441 patients who presented with at least 1 of 3 key symptoms—cough, wheeze, dyspnoea—but had neither documented asthma nor bronchial obstruction. The histamine concentrations causing a 20% fall in forced expiratory volume in 1 second ($PC_{20}FEV_1$) and a 25% fall in maximal mid-inspiratory flow ($PC_{25}MIF_{50}$) were used as respective thresholds of bronchial and EA responsiveness. Values 8 mg/mL or less indicated bronchial (B-HR) or EA hyper-responsiveness (EA-HR). The influence of concurrent upper respiratory tract diseases, such as post-nasal drip (PND), pharyngitis, laryngitis and sinusitis, was also assessed. We found 4 response patterns to the histamine challenge: EA-HR in 26.5% of the patients, B-HR in 11.1%, combined EA-HR and B-HR in 40.6%, and no-HR in 21.8%. Cough was reported by 79% of the patients, wheeze by 53%, and dyspnoea by 40%. Patients with cough as the sole presenting symptom (34.2%), as compared with those with wheeze and/or dyspnoea (20%), had significantly greater probability of having EA-HR (OR 5.35, 95% CI 3.25-8.82) and lower probability of having B-HR (OR 0.45, CI 0.28-0.70); patients with cough plus wheeze and/or dyspnoea (45.8%) had significantly greater probability of having both EA-HR and B-HR than either those with cough alone (OR 2.48, CI 1.49-4.13), or those with wheeze and/or dyspnoea but not cough (OR 1.74, CI 1.36-2.22). EA-HR alone or combined with B-HR was strongly associated with EA diseases, particularly pharyngitis and PND. Cough was significantly associated with PND, either when it was the sole symptom (OR 2.16, CI 1.14-4.09) or when it was combined with wheeze and/or dyspnoea (OR 3.53, CI 1.97-6.33). Our results suggest that extrathoracic airway dysfunction may account for asthma-like symptoms, particularly chronic cough. This abnormality seems to be sustained by chronic diseases of the upper respiratory tract.

**Genetic Susceptibility to Asthma—Bronchial Hyperresponsiveness Coinherited with a Major Gene for Atopy**—DS Postma, ER Bleecker, PJ Amelung, KJ Holroyd, J Xu, CIM Panhuysen, DA Meyers, RC Levitt. N Engl J Med 1995;333(14):894.

BACKGROUND: Bronchial hyperresponsiveness, a risk factor for asthma, consists of a heightened bronchoconstrictor response to a variety of stimuli. The condition has a heritable component and is closely related to serum IgE levels and airway inflammation. The basis for these relations is unknown, as is the mechanism of genetic susceptibility to bronchial hyperresponsiveness. We attempted to define the interrelation between atopy and bronchial hyperresponsiveness and to investigate the chromosomal location of this component of asthma. METHODS: We studied 303 children and grandchildren of 84 probands with asthma selected from a homogeneous population in the Netherlands. Ventilatory function, bronchial responsiveness to histamine, and serum total IgE were measured. The association between the last 2 variables was evaluated. Using analyses involving pairs of siblings, we tested for linkage between bronchial hyperresponsiveness and genetic markers on chromosome 5q31-q33, previously shown to be linked to a genetic locus regulating serum total IgE levels. RESULTS: Serum total IgE levels were strongly correlated ($r = 0.65$, $p < 0.01$) in pairs of siblings concordant for bronchial hyperresponsiveness (defined as a ≥ 20% decrease in the forced expiratory volume in 1 second produced by histamine [threshold dose, ≤ 16 mg/mL]), suggesting that these traits are coinherited. However, bronchial hyperresponsiveness was not correlated with serum IgE levels ($r = 0.04$, $p > 0.10$). Analyses of pairs of siblings showed linkage of bronchial hyperresponsiveness with several genetic markers on chromosome 5q, including D5S436 ($p < 0.001$ for a histamine threshold value of ≤ 16 mg/mL). CONCLUSIONS: This study demonstrates that a trait for an elevated level of serum total IgE is coinherited with a trait for bronchial hyperresponsiveness and that a gene governing bronchial hyperresponsiveness is located near a major locus that

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# Serevent® (salmeterol xinafoate)

## Serevent®
***(salmeterol xinafoate)***
***Inhalation Aerosol***

**BRIEF SUMMARY**

**Bronchodilator Aerosol**
**For Oral Inhalation Only**

The following is a brief summary only. Before prescribing, see complete prescribing information in Serevent® Inhalation Aerosol product labeling.

**CONTRAINDICATIONS:** Serevent® Inhalation Aerosol is contraindicated in patients with a history of hypersensitivity to any of the components.

**WARNINGS:**
**IMPORTANT INFORMATION: SEREVENT® INHALATION AEROSOL SHOULD NOT BE INITIATED IN PATIENTS WITH SIGNIFICANTLY WORSENING OR ACUTELY DETERIORATING ASTHMA, WHICH MAY BE A LIFE-THREATENING CONDITION. Serious acute respiratory events, including fatalities, have been reported, both in the US and worldwide, when Serevent Inhalation Aerosol has been initiated in this situation.**

**Although it is not possible from these reports to determine whether Serevent Inhalation Aerosol contributed to these adverse events or simply failed to relieve the deteriorating asthma, the use of Serevent Inhalation Aerosol in this setting is inappropriate.**

**SEREVENT INHALATION AEROSOL SHOULD NOT BE USED TO TREAT ACUTE SYMPTOMS. It is crucial to inform patients of this and prescribe a short-acting, inhaled $beta_2$-agonist for this purpose as well as warn them that increasing inhaled $beta_2$-agonist use is a signal of deteriorating asthma.**

**SEREVENT INHALATION AEROSOL IS NOT A SUBSTITUTE FOR INHALED OR ORAL CORTICOSTEROIDS. Corticosteroids should not be stopped or reduced when Serevent Inhalation Aerosol is initiated.**

**(See PRECAUTIONS: Information for Patients section of the full prescribing information and the separate PATIENT'S INSTRUCTIONS FOR USE leaflet.)**

1. Do Not Introduce Serevent Inhalation Aerosol as a Treatment for Acutely Deteriorating Asthma: Serevent Inhalation Aerosol is intended for the maintenance treatment of asthma (see INDICATIONS and USAGE section of the full prescribing information) and should not be introduced in acutely deteriorating asthma, which is a potentially life-threatening condition. There are no data demonstrating that Serevent Inhalation Aerosol provides greater efficacy than or additional efficacy to short-acting, inhaled $beta_2$-agonists in patients with worsening asthma. Serious acute respiratory events, including fatalities, have been reported, both in the US and worldwide, in patients receiving Serevent Inhalation Aerosol. In most cases, these have occurred in patients with severe asthma (e.g., patients with a history of corticosteroid dependence, low pulmonary function, intubation, mechanical ventilation, frequent hospitalizations, or previous life-threatening acute asthma exacerbations) and/or in some patients in whom asthma has been acutely deteriorating (e.g., unresponsive to usual medications, increasing need for inhaled short-acting $beta_2$-agonists, increasing need for systemic corticosteroids, significant increase in symptoms, recent emergency room visits, sudden or progressive deterioration in pulmonary function). However, they have occurred in a few patients with less severe asthma as well. It was not possible from these reports to determine whether Serevent Inhalation Aerosol contributed to these events or simply failed to relieve the deteriorating asthma.

2. Do Not Use Serevent Inhalation Aerosol to Treat Acute Symptoms: A short-acting, inhaled $beta_2$-agonist, not Serevent Inhalation Aerosol, should be used to relieve acute asthma symptoms. When prescribing Serevent Inhalation Aerosol, the physician must also provide the patient with a short-acting, inhaled $beta_2$-agonist (e.g., albuterol) for treatment of symptoms that occur acutely, despite regular twice daily (morning and evening) use of Serevent Inhalation Aerosol.

When beginning treatment with Serevent Inhalation Aerosol, patients who have been taking short-acting, inhaled $beta_2$-agonists on a regular basis (e.g., q.i.d.) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief if they develop acute asthma symptoms while taking Serevent Inhalation Aerosol (see PRECAUTIONS: Information for Patients).

3. Watch for Increasing Use of Short-Acting, Inhaled $Beta_2$-Agonists, Which Is a Marker of Deteriorating Asthma: Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient's short-acting, inhaled $beta_2$-agonist becomes less effective or the patient needs more inhalations than usual, this may be a marker of destabilization of asthma. In this setting, the patient requires immediate re-evaluation with reassessment of the treatment regimen, giving special consideration to the possible need for corticosteroids. If the patient uses four or more inhalations per day of a short-acting, inhaled $beta_2$-agonist for 2 or more consecutive days, or if more than one canister (200 inhalations per canister) of short-acting, inhaled $beta_2$-agonist is used in an 8-week period in conjunction with Serevent Inhalation Aerosol, then the patient should consult the physician for re-evaluation. **Increasing the daily dosage of Serevent Inhalation Aerosol in this situation is not appropriate. Serevent Inhalation Aerosol should not be used more frequently than twice daily (morning and evening) at the recommended dose of two inhalations.**



4. Do Not Use Serevent Inhalation Aerosol as a Substitute for Oral or Inhaled Corticosteroids: There are no data demonstrating that Serevent Inhalation Aerosol has a clinical anti-inflammatory effect and could be expected to take the place of, or reduce the dose of corticosteroids. Patients who already require oral or inhaled corticosteroids for treatment of asthma should be continued on this type of treatment even if they feel better as a result of initiating Serevent Inhalation Aerosol. Any change in corticosteroid dosage should be made ONLY after clinical evaluation (see PRECAUTIONS: Information for Patients).

5. Do Not Exceed Recommended Dosage: As with other inhaled $beta_2$-adrenergic drugs, Serevent Inhalation Aerosol should not be used more often or at higher doses than recommended. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Large doses of inhaled or oral salmeterol (12 to 20 times the recommended dose) have been associated with clinically significant prolongation of the QT interval, which has the potential for producing ventricular arrhythmias.

6. Paradoxical Bronchospasm: As with other inhaled asthma medication, paradoxical bronchospasm (which can be life threatening) has been reported following the use of Serevent Inhalation Aerosol. If it occurs, treatment with Serevent Inhalation Aerosol should be discontinued immediately and alternative therapy instituted.

7. Immediate Hypersensitivity Reactions: Immediate hypersensitivity reactions may occur after administration of Serevent Inhalation Aerosol, as demonstrated by rare cases of urticaria, angioedema, rash, and bronchospasm.

8. Upper Airway Symptoms: Symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking, have been reported rarely in patients receiving Serevent Inhalation Aerosol.

**PRECAUTIONS:**

**General:** 1. Use With Spacer or Other Devices: The safety and effectiveness of Serevent® Inhalation Aerosol when used with a spacer or other devices have not been adequately studied.

2. Cardiovascular and Other Effects: No effect on the cardiovascular system is usually seen after the administration of inhaled salmeterol in recommended doses, but the cardiovascular and central nervous system effects seen with all sympathomimetic drugs (e.g., increased blood pressure, heart rate, excitement) can occur after use of Serevent Inhalation Aerosol and may require discontinuation of the drug. Salmeterol, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines.

As has been described with other beta-adrenergic agonist bronchodilators, clinically significant changes in systolic and/or diastolic blood pressure, pulse rate, and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with salmeterol.

3. Metabolic Effects: Doses of the related $beta_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate pre-existing diabetes mellitus and ketoacidosis. No effects on glucose have been seen with Serevent Inhalation Aerosol at recommended doses. Administration of $beta_2$-adrenoceptor agonists may cause a decrease in serum potassium, possibly through intracellular shunting, which has the potential to increase the likelihood of arrhythmias. The decrease is usually transient, not requiring supplementation.

Clinically significant changes in blood glucose and/or serum potassium were seen rarely during clinical studies with long-term administration of Serevent Inhalation Aerosol at recommended doses.

**Information for Patients:** See illustrated Patient's Instructions for Use leaflet. **SHAKE WELL BEFORE USING**

It is important that patients understand how to use Serevent Inhalation Aerosol appropriately and how it should be used in relation to other asthma medications they are taking. Patients should be given the following information:

1. Shake well before using.

2. The recommended dosage (two inhalations twice daily, morning and evening) should not be exceeded.

3. Serevent Inhalation Aerosol is not meant to relieve acute asthma symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with a short-acting, inhaled $beta_2$-agonist such as albuterol (the physician should provide the patient with such medication and instruct the patient in how it should be used).

4. The physician should be notified immediately if any of the following situations occur, which may be a sign of seriously worsening asthma.

- Decreasing effectiveness of short-acting, inhaled $beta_2$-agonists
- Need for more inhalations than usual of short-acting, inhaled $beta_2$-agonists
- Use of four or more inhalations per day of a short-acting $beta_2$-agonist for 2 or more days consecutively
- Use of more than one canister of a short-acting, inhaled $beta_2$-agonist in an 8-week period (i.e., canister with 200 inhalations)

5. Serevent Inhalabon Aerosol should not be used as a substitute for oral or inhaled corticosteroids. The dosage of these medications should not be changed and they should not be stopped without consulting the physician, even if the patient feels better after initiating treatment with Serevent Inhalation Aerosol.

6. Patients should be cautioned regarding potential adverse cardiovascular effects, such as palpitations or chest pain, related to the use of additional $beta_2$-agonist.

7. In patients receiving Serevent Inhalation Aerosol, other inhaled medications should be used only as directed by the physician.

8. When using Serevent Inhalation Aerosol to prevent exercise-induced bronchospasm, patients should take the dose at least 30 to 60 minutes before exercise.

**Drug Interactions:** ***Short-Acting Beta-Agonists:*** In the two 3-month, repetitive-dose clinical trials (n=184), the mean daily need for additional $beta_2$-agonist use was 1 to 1½ inhalations per day, but some patients used more. Eight percent of patients used at least eight inhalations per day at least on one occasion. Six percent used 9 to 12 inhalations at least once. There were 15 patients (8%) who averaged over four inhalations per day. Four of these used an average of 8 to 11 inhalations per day. In these 15 patients there was no observed increase in frequency of cardiovascular adverse

events. The safety of concomitant use of more than eight inhalations per day of short-acting $beta_2$-agonists with Serevent Inhalation Aerosol has not been established. In 15 patients who experienced worsening of asthma while receiving Serevent Inhalation Aerosol, nebulized albuterol (one dose in most) led to improvement in forced expiratory volume in 1 second ($FEV_1$) and no increase in occurrence of cardiovascular adverse events.

***Monoamine Oxidase Inhibitors and Tricyclic Antidepressants:*** Salmeterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants because the action of salmeterol on the vascular system may be potentiated by these agents.

***Corticosteroids and Cromoglycate:*** In clinical trials, inhaled corticosteroids and/or inhaled cromolyn sodium did not alter the safety profile of Serevent Inhalation Aerosol when administered concurrently.

***Methylxanthines:*** The concurrent use of intravenously or orally administered methylxanthines (e.g., aminophylline, theophylline) by patients receiving Serevent Inhalation Aerosol has not been completely evaluated. In one clinical trial, 87 patients receiving Serevent Inhalation Aerosol 42 mcg twice daily concurrently with a theophylline product had adverse event rates similar to those in 71 patients receiving Serevent Inhalation Aerosol without theophylline. Resting heart rates were slightly higher in the patients on theophylline but were little affected by Serevent Inhalation Aerosol therapy.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** In an 18-month oral carcinogenicity study in CD-mice, salmeterol xinafoate caused a dose-related increase in the incidence of smooth muscle hyperplasia, cystic glandular hyperplasia, and leiomyomas of the uterus and a dose-related increase in the incidence of cysts in the ovaries. A higher incidence of leiomyosarcomas was not statistically significant; tumor findings were observed at oral doses of 1.4 and 10 mg/kg, which gave 9 and 63 times, respectively, the human exposure based on rodent:human AUC comparisons.

Salmeterol caused a dose-related increase in the incidence of mesovarian leiomyomas and ovarian cysts in Sprague Dawley rats in a 24-month inhalation/oral carcinogenicity study. Tumors were observed in rats receiving doses of 0.68 and 2.58 mg/kg per day (about 55 and 215 times the recommended clinical dose [mg/m$^2$]). These findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown.

No significant effects occurred in mice at 0.2 mg/kg (1.3 times the recommended clinical dose based on comparisons of the AUCs) and in rats at 0.21 mg/kg (15 times the recommended clinical dose on a mg/m$^2$ basis).

Salmeterol xinafoate produced no detectable or reproducible increases in microbial and mammalian gene mutation *in vitro*. No blastogenic activity occurred *in vitro* in human lymphocytes or *in vivo* in a rat micronucleus test. No effects on fertility were identified in male and female rats treated orally with salmeterol xinafoate at doses up to 2 mg/kg orally (about 160 times the recommended clinical dose on a mg/m$^2$ basis).

**Pregnancy:** ***Teratogenic Effects: Pregnancy Category C:*** No significant effects of maternal exposure to oral salmeterol xinafoate occurred in the rat at doses up to the equivalent of about 160 times the recommended clinical dose on a mg/m$^2$ basis. Dutch rabbit fetuses exposed to salmeterol xinafoate *in utero* exhibited effects characteristically resulting from beta-adrenoceptor stimulation; these included precocious eyelid openings, cleft palate, sternebral fusion, limb and paw flexures, and delayed ossification of the frontal cranial bones. No significant effects occurred at 0.6 mg/kg given orally (12 times the recommended clinical dose based on comparison of the AUCs).

New Zealand White rabbits were less sensitive since only delayed ossification of the frontal bones was seen at 10 mg/kg given orally (approximately 1,600 times the recommended clinical dose on a mg/m$^2$ basis). Extensive use of other beta-agonists has provided no evidence that these class effects in animals are relevant to use in humans. There are no adequate and well-controlled studies with Serevent Inhalation Aerosol in pregnant women. Serevent Inhalation Aerosol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Use in Labor and Delivery:** There are no well-controlled human studies that have investigated effects of salmeterol on preterm labor or labor at term. Because of the potential for beta-agonist interference with uterine contractility, use of Serevent Inhalation Aerosol during labor should be restricted to those patients in whom the benefits clearly outweigh the risks.

**Nursing Mothers:** Plasma levels of salmeterol after inhaled therapeutic doses are very low (85 to 200 pg/mL) in humans. In lactating rats dosed with radiolabeled salmeterol, levels of radioactivity were similar in plasma and milk. In rats, concentrations of salmeterol in plasma and milk were similar. The xinafoate moiety is also transferred to milk in rats at concentrations of about half the corresponding level in plasma. However, since there is no experience with use of Serevent Inhalation Aerosol by nursing mothers, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when salmeterol xinafoate is administered to a nursing woman.

**Pediatric Use:** The safety and effectiveness of Serevent Inhalation Aerosol in children younger than 12 years of age have not been established.

**Geriatric Use:** Of the total number of patients who received Serevent Inhalation Aerosol in all clinical studies, 241 were 65 years and older. Geriatric patients (65 years and older) with reversible obstructive airway disease were evaluated in four well-controlled studies of 3 weeks' to 3 months' duration. Two placebo-controlled, crossover studies evaluated twice-daily dosing with salmeterol for 21 to 28 days in 45 patients. An additional 75 geriatric patients were treated with salmeterol for 3 months in two large parallel-group, multicenter studies. These 120 patients experienced increases in AM and PM peak expiratory flow rate and decreases in diurnal variation in peak expiratory flow rate similar to responses seen in the total populations of the two latter studies. The adverse event type and frequency in geriatric patients were not different from those of the total populations studied.

No apparent differences in the efficacy and safety of Serevent Inhalation Aerosol were observed when geriatric patients were compared with younger patients in clinical trials. As with other $beta_2$-agonists, however, special caution should be observed when using Serevent Inhalation Aerosol in elderly patients who have concomitant cardiovascular disease that could be adversely affected by this class of drug. Based on available data, no adjustment of salmeterol dosage in geriatric patients is warranted.

**ADVERSE REACTIONS:** Adverse reactions to salmeterol are similar in nature to reactions to other selective $beta_2$-adrenoceptor agonists, i.e., tachycardia; palpitations; immediate hypersensitivity reactions, including urticaria, angioedema, rash, bronchospasm (see WARNINGS); headache; tremor; nervousness; and paradoxical bronchospasm (see WARNINGS).

Two multicenter, 12-week, controlled studies have evaluated twice-daily doses of Serevent® Inhalation Aerosol in patients 12 years of age and older with asthma. The following table reports the incidence of adverse events in these two studies.

**Serevent® (salmeterol xinafoate) Inhalation Aerosol**

**Adverse Experience Incidence in Two Large 12-Week Clinical Trials***

| Adverse Event Type | Percent of Patients | | |
|---|---|---|---|
| | Placebo n=187 | Serevent 42 mcg b.i.d. n=184 | Albuterol 180 mcg q.i.d. n=185 |
| Ear, nose, and throat | | | |
| Upper respiratory tract infection | 13 | 14 | 16* |
| Nasopharyngitis | 12 | 14 | 11 |
| Disease of nasal cavity/sinus | 4 | 6 | 1 |
| Sinus headache | 2 | 4 | <1 |
| Gastrointestinal | | | |
| Stomachache | 0 | 4 | 0 |
| Neurological | | | |
| Headache | 23 | 28 | 27 |
| Tremor | 2 | 4 | 3 |
| Respiratory | | | |
| Cough | 6 | 7 | 3 |
| Lower respiratory infection | 2 | 4 | 2 |

* The only adverse experience classified as serious was one case of upper respiratory tract infection in a patient treated with albuterol.

The table above includes all events (whether considered drug related or nondrug related by the investigator) that occurred at a rate of over 3% in the Serevent Inhalation Aerosol treatment group and were more common in the Serevent Inhalation Aerosol group than in the placebo group.

Pharyngitis, allergic rhinitis, dizziness/giddiness, and influenza occurred at 3% or more but were equally common on placebo. Other events occurring in the Serevent Inhalation Aerosol treatment group at a frequency of 1% to 3% were as follows:

***Cardiovascular:*** Tachycardia, palpitations.
***Ear, Nose, and Throat:*** Rhinitis, laryngitis.
***Gastrointestinal:*** Nausea, viral gastroenteritis, nausea and vomiting, diarrhea, abdominal pain.
***Hypersensitivity:*** Urticaria.
***Mouth and Teeth:*** Dental pain.
***Musculoskeletal:*** Pain in joint, back pain, muscle cramp/contraction, myalgia/myositis, muscular soreness.
***Neurological:*** Nervousness, malaise/fatigue.
***Respiratory:*** Tracheitis/bronchitis.
***Skin:*** Rash/skin eruption.
***Urogenital:*** Dysmenorrhea.
In small dose-response studies, tremor, nervousness, and palpitations appeared to be dose related.

**Postmarketing Experience:** In extensive US and worldwide postmarketing experience, serious exacerbations of asthma, including some that have been fatal, have been reported. In most cases, these have occurred in patients with severe asthma and/or in some patients in whom asthma has been acutely deteriorating (see WARNINGS no. 1), but they have occurred in a few patients with less severe asthma as well. It was not possible from these reports to determine whether Serevent Inhalation Aerosol contributed to these events or simply failed to relieve the deteriorating asthma.

Postmarketing experience includes rare reports of upper airway symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking.

**OVERDOSAGE:** Overdosage with salmeterol may be expected to result in exaggeration of the pharmacologic adverse effects associated with beta-adrenoceptor agonists, including tachycardia and/or arrhythmia, tremor, headache, and muscle cramps. Overdosage with salmeterol can lead to clinically significant prolongation of the $QT_c$ interval, which can produce ventricular arrhythmias. Other signs of overdosage may include hypokalemia and hyperglycemia.

In these cases, therapy with Serevent® Inhalation Aerosol and all beta-adrenergic–stimulant drugs should be stopped, supportive therapy provided, and judicious use of a beta-adrenergic blocking agent should be considered, bearing in mind the possibility that such agents can produce bronchospasm. Cardiac monitoring is recommended in cases of overdosage.

As with all sympathomimetic pressurized aerosol medications, cardiac arrest and even death may be associated with abuse of Serevent Inhalation Aerosol.

Rats and dogs survived the maximum practicable inhalation doses of salmeterol of 2.9 and 0.7 mg/kg, respectively. The maximum nonlethal oral doses in mice and rats were approximately 150 mg/kg and >1,000 mg/kg, respectively.

Dialysis is not appropriate treatment for overdosage of Serevent Inhalation Aerosol.

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regulates serum IgE levels on chromosome 5q. These findings are consistent with the existence of 1 or more genes on chromosome 5q31-q33 causing susceptibility to asthma.

**The Relationship between Infection and Inflammation in the Early Stages of Lung Disease from Cystic Fibrosis**—K Balough, M McCubbin, M Weinberger, W Smits, R Ahrens, R Fick. Pediatr Pulmonol 1995;20(2):63.

We examined the relationship of pulmonary infection and inflammation in cystic fibrosis (CF) by performing 31 bronchoalveolar lavages (BAL) in 14 young children with minimal lung disease from CF. While 10 of the 14 patients had elevated polymorphonuclear leukocyte (PMN) counts initially, only 4 had bacteria generally regarded as pathogenic in the recovered BAL fluid. Three of these 4 and 6 of the others had follow-up bronchoscopies at 6 months intervals. PMN counts remained normal for only 1 patient. However, pathogenic bacteria were recovered during the repeat BALs only in those patients who were colonized initially. Proinflammatory cytokines and proteinases were generally elevated, and interleukin-8 (IL-8) concentration correlated inversely with oxygen saturation ($S_{pO_2}$). No complications of the procedure occurred. We conclude that BAL identifies inflammation and the presence of bacteria in the lower airway at an early stage of the disease. This information may be used to guide therapy in patients too young or otherwise unable to produce sputum. These data also suggest that inflammation is present early in the course of CF lung disease before colonization and infection of the lungs with potentially pathogenic bacteria occurs. Since inflammation appears to be the earliest detectable evidence of lung disease in CF, monitoring of inflammation with BAL may serve as a useful marker of clinical benefits from new treatments in patients with minimal lung disease.

**The Use of High-Efficiency Particulate Air-Filter Respirators To Protect Hospital Workers from Tuberculosis: A Cost-Effectiveness Analysis**—KA Adal, AM Anglim, CL Palumbo, MG Titus, BJ Coyner, BM Farr. N Engl J Med 1994;331(3):169.

BACKGROUND: After outbreaks of multidrug-resistant tuberculosis, the Centers for Disease Control and Prevention proposed the use of respirators with high-efficiency particulate air filters (HEPA respirators) as part of isolation precautions against tuberculosis, along with a respiratory-protection program for health care workers that includes medical evaluation, training, and tests of the fit of the respirators. Each HEPA respirator costs between $7.51 and $9.08, about 10 times the cost of respirators currently used. METHODS: We conducted a cost-effectiveness analysis using data from the University of Virginia Hospital on exposure to patients with tuberculosis and rates at which the purified-protein-derivative (PPD) skin test became positive in hospital workers. The costs of a respiratory-protection program were based on those of an existing program for workers dealing with hazardous substances. RESULTS: During 1992, 11 patients with documented tuberculosis were admitted to our hospital. Eight of 3,852 workers (0.2%) had PPD tests that became positive. Five of these conversions were believed to be due to the booster phenomenon; 1 followed unprotected exposure to a patient not yet in isolation; the other 2 occurred in workers who had never entered a tuberculosis isolation room. These data suggest that it will take more than 1 year for the use of HEPA respirators to prevent a single conversion of the PPD test. Assuming that 1 conversion is prevented per year, however, it would take 41 years at our hospital to prevent 1 case of occupationally acquired tuberculosis, at a cost of $1.3 million to $18.5 million. CONCLUSIONS: Given the effectiveness of currently recommended measures to prevent nosocomial transmission of tuberculosis, the addition of HEPA respirators would offer negligible protective efficacy at great cost.

**Clinical Trial of a New Lightwand Device (Trachlight) To Intubate the Trachea**—OR Hung, S Pytka, J Morris, M Murphy, G Launcelott, S Stevens, W MacKay, RD Stewart. Anesthesiology 1995;83(3):509.

BACKGROUND: Transillumination of the soft tissue of the neck using a lighted stylet (lightwand) is an effective and safe intubating technique. A newly designed lightwand (Trachlight) incorporates modifications to improve the brightness of the light source as well as flexibility. The goal of this study was to determine the effectiveness and safety of this device in intubating the trachea of elective surgical patients. METHODS: Healthy surgical patients were studied. Patients with known or potential problems with intubation were excluded. During general anesthesia, the tracheas were intubated randomly using either the Trachlight or the laryngoscope. Failure to intubate was defined as lack of successful intubation after 3 attempts. The duration of each attempt was recorded as the time from insertion of the device into the oropharynx to the time of its removal. The total time to intubation (TTI), an overall measure of the ease of intubation, was defined as the sum of the durations of all (as many as 3) intubation attempts. Complications, such as mucosal bleeding, lacerations, dental injury, and sore throat, were recorded. RESULTS: Nine hundred fifty patients (479 in the Trachlight group and 471 in the laryngoscope group) were studied. There was a 1% failure rate with the Trachlight, and 92% of intubations were successful on the first attempt, compared with a 3% failure rate and an 89% success rate on the first attempt with the laryngoscope (p not significant). All failures were followed by successful intubation using the alternate device. The TTI was significantly less with the Trachlight compared with the laryngoscope (15.7 ± 10.8 vs 19.6 ± 23.7 s). For laryngoscopic intubation, the TTI was longer for patients with limited mandibular protrusion and mentohyoid distance, with a larger circumference of the neck, and with a high classification according to Mallampatti et al. However, there was no relation between the TTI and any of the airway parameters for Trachlight. There were significantly fewer traumatic events in the Trachlight group than in the laryngoscope group (10 vs 37). More patients complained of sore throat in the laryngoscope group than in the Trachlight group (25.3% vs 17.1%). CONCLUSIONS: In contrast to laryngoscopy, the ease of intubation using the Trachlight does not appear to be influenced by anatomic variations of the upper airway. Intubation occasionally failed with the Trachlight but in all cases was resolved with direct laryngoscopy. The failures of direct laryngoscopy were resolved with Trachlight. Thus the combined technique was 100% successful in intubating the tracheas of all patients.

**Cardiorespiratory Effects of Positive End-Expiratory Pressure during Progressive Tidal Volume Reduction (Permissive Hypercapnia) in Patients with Acute Respiratory Distress Syndrome**—VM Ranieri, L Mascia, T Fiore, F Bruno, A Brienza, R Giuliani. Anesthesiology 1995;83(4):710.

BACKGROUND: In patients with acute respiratory distress syndrome (ARDS) the ventilatory approach is based on tidal volume ($V_T$) of 10-15 mL/kg and positive end-expiratory pressure (PEEP). To avoid further pulmonary injury decreasing $V_T$ and allowing $P_{aCO_2}$ to increase (permissive hypercapnia) has been suggested. Effects of 10 cm $H_2O$ of PEEP on respiratory mechanics, hemodynamics, and gas exchange were compared during mechanical ventilation with conventional (10-15 mL/ kg) and low (5-8 mL/kg) $V_T$. METHODS: Nine sedated and paralyzed patients were studied. $V_T$ was decreased gradually (50 mL every 20-30 min). Static volume pressure (V-P) curves, hemodynamics, and gas exchange were measured. RESULTS: During mechanical ventilation with conventional $V_T$, V-P curves on PEEP 0 (ZEEP) exhibited an upward convexity in 6 patients reflecting a progressive reduction in compliance with inflating volume; whereas, PEEP resulted in a volume displacement along the flat part of this curve. After $V_T$ reduction, V-P curves in the same patients showed an upward concavity, reflecting progressive alveolar recruitment with inflating volume, and application of PEEP resulted in alveolar recruitment. The other 3 patients showed a V-P curve with an upward concavity; $V_T$ reduction increased this concavity and application of PEEP induced greater alveolar recruitment than during conventional $V_T$. With PEEP, cardiac index decreased by, respectively, 31% during conventional $V_T$ and 11% during low $V_T$ (p <

0.01); $P_{aO_2}$, increased by 32% and 71% ($p < 0.01$) respectively; whereas, right-to-left venous admixture ($\dot{Q}_s/\dot{Q}_t$) decreased by 11% and 40% respectively ($p < 0.01$). The greatest values of $P_{aO_2}$ static compliance and oxygen delivery and the lowest values of $\dot{Q}_s/\dot{Q}_t$ (best PEEP) were obtained during application of PEEP with low $V_T$ ($p < 0.01$). CONCLUSIONS: Although PEEP induced alveolar hyperinflation in most patients during mechanical ventilation with conventional $V_T$, at low $V_T$, there appeared to be a significant alveolar collapse and PEEP was able to expand these units improving gas exchange and hemodynamics.

**Bronchoalveolar Lavage Studies in Children without Parenchymal Lung Disease: Cellular Constituents and Protein Levels**—F Midulla, A Villani, R Merolla, L Bjermer, T Sandstrom, R Ronchetti. Pediatr Pulmonol 1995;20(2):112.

We evaluated bronchoalveolar lavage fluid (BAL) for cellular constituents, concentration of total protein (TP), albumin (AL), fibronectin (FN), and hyaluronic acid (HA) in 16 children aged 2-32 months without pulmonary inflammatory or parenchymal disease to establish reference values. We compared our data to those reported in older children and in normal adult volunteers. BAL results were obtained simultaneously from the right middle lobe and the lingula. Results indicated that children younger than 3 years of age had a higher number of cells/mL than older children and adults ($59.9 \times 10^4$ vs $17.6 \times 10^4$ and $12 \times 10^4$). Differential cell count revealed that the percentages of alveolar macrophages (AM), lymphocytes (LYM), and eosinophils (EOS) were similar to those obtained in older children and in adults; whereas, the percentage of neutrophils (NEU) was higher in younger children (NEU 5.5 vs 1.6 and 1.2%, respectively) than in older children and adults. The latter difference was even greater in infants under 12 months of age (NEU 7.6%). The concentrations of TP, AL, FN, and HA in children's BAL samples were compared to values reported for adults. There were no differences between infants and children 13-32 months of age or normal adults. BAL fluid obtained simultaneously from the middle lobe and lingula were not significantly different. In conclusion, this is the first report on BAL values (cellular and noncellular constituents) in children younger than 3 years. The results may be used as reference values for further studies in children with parenchymal lung disease in this age group.

**School-Based Screening for Tuberculous Infection: A Cost-Benefit Analysis**—JC Mohle-Boetani, B Miller, M Halpern, A Trivedi, J Lessler, SL Solomon, M Fenstersheib. JAMA 1995;274 (8):613.

OBJECTIVE: To compare tuberculin screening of all kindergartners and high school entrants (screen-all strategy) vs screening limited to high-risk children (targeted screening). DESIGN: Decision, cost-effectiveness, and cost-benefit analyses. SETTING & SUBJECTS: Students in a large urban and rural county. DEFINITIONS: High risk of tuberculous infection was defined as birth in a country with a high prevalence of tuberculosis. Low risk was defined as birth in the United States. OUTCOME MEASURES: Tuberculosis cases prevented per 10,000 children screened, Net costs, net cost per case prevented, benefit-cost ratio, and incremental cost-effectiveness. RESULTS: The screen-all strategy would prevent 14.9 cases per 10,000 children screened; targeted screening would prevent 84.9 cases per 10,000 children screened. The screen-all strategy is more costly than no screening; the benefit-cost ratio is 0.58. Targeted screening would result in a net savings; the benefit-cost ratio is 1.2. Screening all children is cost-saving only if the reactor rate is 20% or greater. The cost per additional case prevented for screening all children compared with targeted screening ($34,666) is more than twice as high as treatment and contact tracing for a case of tuberculosis ($16,392). CONCLUSIONS: Targeted screening of schoolchildren is much less costly than mass screening and is more efficient in prevention of tuberculosis.

**A Critical Assessment of Uncalibrated Respiratory Inductance Plethysmography (Respitrace®) for the Measurement of Tidal Breathing Parameters in Newborns and Infants**—E Jackson, J Stocks, L Pilgrim, I Dundas, C Dezateux. Pediatr Pulmonol 1995;20(2):119.

We have compared results obtained with an uncalibrated respiratory inductance plethysmograph (RIP) with those of a face mask and pneumotachograph (PNT) for the computerized measurement of the time to reach peak tidal expiratory flow as a ratio of total expiratory time ($t_{PTEF}:t_E$). Simultaneous measurements were made in 32 healthy neonates aged 0-3 weeks, 35 healthy infants aged 5-82 weeks, and 28 infants aged 15-94 weeks with physician-diagnosed recurrent wheeze. The group mean (±SD) values of $t_{PTEF}:t_E$ determined using a PNT were 0.455 (±0.129), 0.263 (±0.077), and 0.232 (±0.089) for the neonates, healthy infants and infants with recurrent wheeze respectively. RIP gave mean (±SD) values that were 0.055 (±0.044) and 0.025 (±0.104) lower than the PNT in healthy neonates and infants with recurrent wheeze respectively; RIP values were 0.002 (±0.073) higher in the healthy infants over 4 weeks of age than measurements by PNT. Although the difference between the 2 measurements was not related to the thoracoabdominal phase angle, as measured from Lissajous figures, examination of the RIP ribcage and abdominal signals revealed that many healthy subjects, while appearing clinically in phase, had ribcage and abdominal signals that differed markedly from each other in terms of convexity/concavity during early expiration. This may explain the lack of agreement between the 2 methods. We conclude that uncalibrated RIP should be used with caution for the determination of $t_{PTEF}:t_E$, even in subjects whose ribcage and abdomen appear to move synchronously. The measurement of $t_{PTEF}:t_E$ did not differentiate between the healthy infants and infants with recurrent wheezing.

**Effect of Aminophylline on High-Energy Phosphate Metabolism and Fatigue in the Diaphragm**—T Ide, DG Nichols, JR Buck, SM Eleff, DC Shungu, JL Robotham, RS Fitzgerald, RJ Traystman. Anesthesiology 1995;83 (3):557.

BACKGROUND: Diaphragmatic fatigue causes respiratory failure, for which aminophylline has been used as therapy. Because the mechanism of action of aminophylline in reversing diaphragmatic fatigue is unclear, we used in vivo $^{31}P$ magnetic resonance spectroscopy (MRS) to determine the relation between diaphragmatic activation, force output, and aerobic metabolism. METHODS: Bilateral phrenic stimulation was used to pace the diaphragm in pentobarbital-anesthetized piglets (6-10 weeks old; n = 44). Esophageal and abdominal pressures were measured to calculate transdiaphragmatic pressure (Pdi) (Pdi = abdominal pressure − esophageal pressure) as an index of force output. Activation was determined by the amplitude of the compound action potential of the diaphragmatic electromyogram. Aerobic metabolism was assessed with a $^{31}P$ MRS surface coil on the right hemidiaphragm with the animal in a 4.7-T magnet. The animals were divided into 4 groups based on aminophylline loading dose: saline, aminophylline 10 mg/kg (A10), aminophylline 20 mg/kg (A20), and aminophylline 40 mg/kg (A40). After aminophylline loading the diaphragm was paced for 25 minutes followed by a 10-minute recovery. RESULTS: Aminophylline concentrations were 12.2 ± 0.7, 21.9 ± 2.4, and 44.9 ± 3.6 mg/L in the A10, A20, and A40 groups, respectively. Compound action potential amplitude decreased in all groups by 30% after 25 minutes of pacing. Conversely, Pdi remained at 100 ± 3% of the initial value after 5 minutes of pacing in the A40 group but decreased to 75 ± 3% in the saline group. Pdi recovered completely (103 ± 17%) in the A40 group but remained depressed (72 ± 6%) in the saline group. Pdi values were intermediate in the A10 and A20 groups. MRS data revealed inadequate energy supply/demand ratio in the saline group such that the ratio of inorganic phosphate to phosphocreatine (Pi/PCr) increased to 1.01 ± 0.09 after 5 minutes of pacing. Pi/PCr remained unchanged in the A40 group and was intermediate in the A10 and A20 groups. β-Adenosine triphosphate and intracellular pH did not differ among groups or as a function of pacing. Diaphragmatic blood flow increased from a resting value of 35-60 to 300-410 mL · min $^{-1}$ · 100 g $^{-1}$ during pacing in all groups and was not

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# ABSTRACTS & POSTER PRESENTATIONS

The AARC Education Section is looking for educational research and experience with models and instructional methods that may be useful in implementing the recommendations of the Education Consensus Conferences or other issues in respiratory care education. **Special consideration will be given to abstracts and poster presentations that deal with multiskill curriculum and/or core curriculum.**

The 1996 Summer Forum, scheduled for July 12–14 in Naples, FL, will offer two opportunities for participants to share their scholarly activities with colleagues:

1. Research abstract presentations dealing with respiratory care education. (Paper presentations will be limited to 15 minutes, including five minutes for discussion.)
2. Poster presentations dealing with education models, methods, or materials that can be shared for noncommercial use. (Individual topics and presenters will be briefly introduced; additional time will be allowed for individual review of posters or display materials and interaction with the presenters.)

**Research abstracts and poster presentation proposals must be submitted by April 15, 1996, for review by the Education Section Review Committee. All abstracts and proposals will be peer-reviewed, and authors will be notified of decisions by May 15. Questions may be directed to the review committee chair, Pat Munzer.**

### Proposals must include three components:

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   b. Title of presentation
   c. Names, primary titles, work addresses, and day telephone numbers of the authors; the name of the author who will present the paper and receive correspondence should be listed first
   d. A statement of previous presentations or publications of the same or similar work
   **e. Two true/false questions with answers**
   f. Other information required by funding sources
2. Camera-ready copy (without author identification) for review by the committee
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# ABSTRACTS & POSTER PRESENTATIONS

## Research Abstracts

Type abstract double-spaced on plain white paper with one-inch margins. The abstract should be written as a single paragraph and limited to 300 words. The research abstract should include the following:

a. Title of paper
b. Brief description of work
c. Brief statement of methodology and findings
d. Conclusions
**e. Two true/false questions with answers**

A maximum of two pages of camera-ready charts and tables may be attached to aid in the selection of the abstract.

## Poster Presentations

Type abstract double-spaced on plain white paper with one-inch margins. The abstract should be written as a single paragraph and limited to 150 words. The poster presentation abstract should include the following:

a. Title of paper
b. Brief description of the model, method, or material
c. Brief statement of how it was developed and implemented
d. Brief statement of how it was evaluated or judged to be of unique value
e. Recommendations for future application
**f. Two true/false questions with answers**

On a separate sheet, describe how the information will be visually presented at the conference.

Each manuscript should be double-checked for completeness and accuracy before it is submitted.

Spell out terms used for the first time, followed by abbreviations in parentheses, e.g., norm-referenced testing (NRT). Thereafter, the term may be abbreviated throughout.

**Please send the abstract and cover sheet to:**

**Pat Munzer, MS, RRT, Program Director**
**Respiratory Therapy**
**Washburn University**
**1700 College**
**Topeka, KS 66621**
**(913) 231-1010, ext. 1284**

affected by aminophylline dose. CONCLUSIONS: Aminophylline, in a dose-dependent fashion, delays the onset of fatigue and improves recovery from fatigue. Delayed fatigue is associated with improved aerobic metabolism as reflected in a low Pi/PCr ratio.

**Blunted Peripheral Chemoreceptor Response to Hyperoxia in a Group of Infants with Bronchopulmonary Dysplasia**—M Katz-Salamon, B Jonsson, H Lagercrantz. Pediatr Pulmonol 1995;20(2):101.

Infants with BPD often suffer from chronic hypoxia and require supplemental oxygen ($O_2$). This might affect the sensitivity of peripheral chemoreceptors. Therefore, we assessed peripheral chemoreceptor function in 25 infants with bronchopulmonary dysplasia (BPD) of varying severity, using the hyperoxic test. These infants were compared with 35 preterm infants who did not develop BPD. All infants were tested during the 40th week of postconceptional age and their mean postnatal age was 81.5 ± 16.3 days. Sixty percent (15/25) of the BPD infants lacked a hyperoxic response, while the proportion of nonresponders to $O_2$ among the other groups was 20% (7/35). The intensity of this response was negatively correlated to time spent on a ventilator and positively to time without supplemental oxygen. The intensity of chemoreceptor function was closely related to the severity of BPD; none of the infants with the most severe form of BPD (grade 3) showed a ventilatory response to hyperoxia. Furthermore, infants with BPD needed significantly longer time to increase their saturation than did non-BPD infants (4.7 and 9.3 s respectively). We conclude that many infants with BPD, particularly those with the most severe form of the disease, have abnormally functioning peripheral chemoreceptors.

**Impaired Action of Thyroid Hormone Associated with Smoking in Women with Hypothyroidism**—B Muller, H Zulewski, P Huber, JG Ratcliffe, JJ Staub. N Engl J Med 1995; 333:964.

BACKGROUND: The effect of smoking on thyroid function is controversial, and its effect on thyroid hormone action is unknown. We investigated the effects of cigarette smoking in women with various grades of hypothyroidism and in normal women. METHODS: We studied 138 normal women and 135 women with primary hypothyroidism, of whom 84 had subclinical hypothyroidism and 51 overt hypothyroidism. Sixty of the women with hypothyroidism were reevaluated during thyroxine therapy. The women were categorized as smokers or nonsmokers according to their responses to a questionnaire. Thyroid function was evaluated by measurements of serum thyrotropin, free thyroxine, and tri-iodothyronine. Peripheral thyroid hormone action was assessed by a clinical score and measurements of ankle-reflex time and serum lipids and creatine kinase. RESULTS: Among the women with subclinical hypothyroidism, the smokers had a higher mean (±SD) serum thyrotropin concentration (21.3 ± 16.6 vs 12.7 ± 7.2 mU/L, $p = 0.004$) and a higher ratio of serum tri-iodothyronine to serum free thyroxine (by 30%, $p = 0.003$) than the nonsmokers. Their serum concentrations of total cholesterol and low-density lipoprotein (LDL) cholesterol were higher (by 16%, $p = 0.013$; and 28%, $p = 0.003$, respectively). Among the women with overt hypothyroidism, the serum concentrations of thyrotropin, free thyroxine, and tri-iodothyronine were similar in the smokers and nonsmokers. As compared with the nonsmokers, the smokers had a clinical score indicating a greater degree of hypothyroidism ($p < 0.001$), higher serum concentrations of total and LDL cholesterol (by 25%, $p < 0.001$; and 24%, $p = 0.002$, respectively), longer ankle-reflex time (by 25%, $p < 0.001$), and higher serum concentrations of creatine kinase (by 236%, $p < 0.001$). There were dose-response relations between smoking and serum concentrations of total and LDL cholesterol, serum creatine kinase concentrations, and ankle-reflex time in the women with overt hypothyroidism, and between smoking and serum concentrations of total and LDL cholesterol in the women with subclinical hypothyroidism. CONCLUSIONS: Smoking increases the metabolic effects of hypothyroidism in a dose-dependent way. This may be explained by alteration of both thyroid function and hormone action.

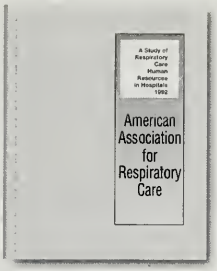
**Efficacy of Combined Coronary Revascularization and Valve Procedures in Octogenarians**—MS Adkins, D Amalfitano, NA Harnum, GW Laub, LB McGrath. Chest 1995;108(4):927.

From January 1982 to October 1991, 42 consecutive patients 80 years of age and older underwent a combined cardiac procedure with coronary revascularization and valve repair or replacement. There were 20 women and 22 men. Mean age at operation was 82.8 years (range, 80 to 89.7 years). Twenty-seven patients (64%) were in New York Heart Association (NYHA) functional class III or IV preoperatively. Six patients (14.3%) had undergone previous cardiac procedures. There were 6 hospital deaths (14.3%). The only significant preoperative risk factor identified for the event hospital death was aortic insufficiency ($p = 0.005$). The 36 hospital survivors were followed up at a mean of 21.1 months after hospital discharge. There were 9 (21%) late deaths occurring at a mean of 21.3 months postoperatively: 2 from acute myocardial infarctions and 7 from chronic heart failure. Survival analysis indicated that higher preoperative NYHA class ($p = 0.0003$), hypertension ($p = 0.015$), hypercholesterolemia ($p = 0.03$), and elevated left atrial/left ventricular gradient ($p = 0.04$) were incremental risk factors for overall mortality. The actuarial survival at 40 months was 51.9%, with no significant difference as compared with an age-, sex-, and race-matched population. Of the 27 late survivors, 26 were in NYHA class I or II. We conclude that octogenarians may undergo complex cardiac surgical procedures with an expectation of an acceptable mortality rate and significant improvement in their functional status. These results must be taken into consideration in light of reported strategies to ameliorate health-care costs by limiting availability of complex medical care to the elderly.

**A Trial of Goal-Oriented Hemodynamic Therapy in Critically Ill Patients**—L Gattinoni, L Brazzi, P Pelosi, R Latini, G Tognoni, A Pesenti, R Fumagalli for the $SvO_2$ Collaborative Group. N Engl J Med 1995;333(16):1025.

BACKGROUND: Hemodynamic therapy to raise the cardiac index and oxygen delivery to supranormal levels may improve outcomes in critically ill patients. We studied whether increasing the cardiac index to a supranormal level (cardiac-index group) or increasing mixed venous oxygen saturation to a normal level (oxygen-saturation group) would decrease morbidity and mortality among critically ill patients, as compared with a control group in which the target was a normal cardiac index. METHODS: A total of 10,726 patients in 56 intensive care units were screened, among whom 762 patients belonging to predefined diagnostic categories with acute physiology scores of 11 or higher were randomly assigned to the 3 groups (252 to the control group, 253 to the cardiac-index group, and 257 to the oxygen-saturation group). RESULTS: The hemodynamic targets were reached by 94.3% of the control group, 44.9% of the cardiac-index group, and 66.7% of the oxygen-saturation group ($p < 0.001$). Mortality was 48.4, 48.6, and 52.1%, respectively ($p = 0.638$), up to the time of discharge from the intensive care unit and 62.3, 61.7, and 63.8% ($p = 0.875$) at 6 months. Among patients who survived, the number of dysfunctional organs and the length of the stay in the intensive care unit were similar in the 3 groups. No differences in mortality among the 3 groups were found for any diagnostic category. A subgroup analysis of the patients in whom hemodynamic targets were reached revealed similar mortality rates: 44.8, 40.4, and 39.0%, respectively ($p = 0.478$). CONCLUSIONS: Hemodynamic therapy aimed at achieving supranormal values for the cardiac index or normal values for mixed venous oxygen saturation does not reduce morbidity or mortality among critically ill patients. *See the related editorial:* ***Manipulating Hemodynamics and Oxygen Transport in Critically Ill Patients****—C Hinds, D Watson. N Engl J Med 1995;333(16):1074-1075.*

## The AARC Human Resources Survey: A Study of Respiratory Care Human Resources in Hospitals




Covers a wide range of human resource issues, including compensation, numbers of full-time equivalents, job vacancy rates, education, credentialing, and licensure. Even includes information on age, sex, and years of experience. Includes comprehensive summary, position profiles, salaries, education, experience, credentials, and regional demographics. Vacancies are inventoried. 68 pages, 66 tables.

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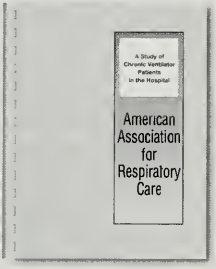
## A Study of Chronic Ventilator Patients in the Hospital




Chronic ventilator-dependent patients are costing American hospitals more than $9 million per day according to this Gallup study conducted for the AARC. This important study provides information on patients who depend on life-support systems; why, how, and where they are being treated; and the cost of treatment. 47 pages, 9 tables, 12 figures.

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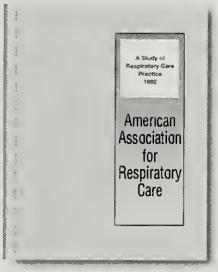


This study examines the practice of respiratory care in today's health care environment and how hospital reorganization is affecting the profession. Includes chapters on medical direction, current respiratory care services, nontraditional services, respiratory care protocols, and hospital service reorganization. 38 pages, 34 tables, 15 charts.

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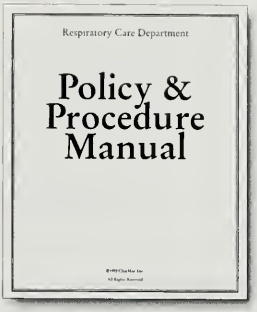


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# Clinical Practice Guidelines: Why, Whence, and Whither?

Perhaps the largest, most discussed, and most costly project initiated by the American Association for Respiratory Care (AARC) in the past 10 years has been the development of AARC Clinical Practice Guidelines (CPGs).[1] CPGs are systematically developed statements to assist clinicians with appropriate respiratory care for specific clinical circumstances. The intended audience for the CPGs developed by the AARC includes everyone involved with the delivery of respiratory care. In addition to respiratory therapists, they should be of interest to physicians—in particular physicians such as pulmonologists and anesthesiologists who are intimately involved with the practice of respiratory care. Clinical practice guidelines are currently fashionable and are being developed by the government and a number of other organizations for a variety of objectives.[2-10] The AARC CPGs are developed for the noblest of reasons—to improve the quality of respiratory care administered to patients. The titles and citations for the 36 previously published CPGs are listed on Page 1299, and the 6 recently approved appear on Pages 1300-1343 of this issue.

### An Overview of Clinical Practice Guidelines

Variability of clinical practice, from one hospital to another and from one geographic region to another, is well known.[10-17] There are differences in patient outcomes, hospital lengths of stay, and costs of care. It is well known that respiratory care practice varies from one hospital to another, and sometimes from one clinical unit to another within a particular hospital. Variations in practice have received increasing public scrutiny. As stated by McGuire,[3] "Our problem is not that the emperor has no clothes, but that because the emperor is increasingly supported at public expense, we must give him guidelines that make his clothes fit our needs as well as his." Where there are differences in practice, the question of which practice is most appropriate is raised by patients, clinicians, third-party payers, and regulating agencies.

The AARC has taken a leadership position in the development of clinical practice guidelines to improve the appropriateness of respiratory care practice throughout the country. Overuse and misallocation of respiratory care has been reported.[18-21] In a retrospective review from the Cleveland Clinic, 25% of respiratory care orders were inappropriate, and another 11% of patients who might have benefited from respiratory care had no orders for such. One solution for this problem may be delegation of more patient care decision making to respiratory therapists in the form of evaluate-and-treat programs, respiratory therapy consultation services, or therapist-driven (ie, patient-driven) protocol programs.[22-24] Even in the absence of such programs, therapist-physician interactions can improve the appropriateness of respiratory care orders.[25] CPGs should provide a basis for determination of appropriate care and the allocation of that care.

In December 1989, the United States Congress established the Agency for Health Care Policy and Research (AHCPR) in an effort to enhance the quality, appropriateness, and effectiveness of health-care services.[7] AHCPR supports clinical practice guidelines that focus on health problems and interventions for which the risks and costs are particularly high, and treatments for which the outcomes of care are particularly variable or uncertain. Although it is important to appreciate that there is a federal initiative to develop guidelines, the development of CPGs by the AARC is *not* affiliated with the AHCPR. AARC CPGs differ in style and form from those of the AHCPR. AHCPR clinical practice guidelines are lengthy and detailed documents; whereas, the AARC CPGs are brief but practical documents that address specific respiratory care modalities. As of December 1994, AHCPR had developed 16 guidelines—none of which related to respiratory care, critical care, pulmonary medicine, or anesthesia.

Through its Agenda for Change, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) is promulgating the development of clinical indicators as quantitative measures to monitor and evaluate the quality of patient care.[26] Clinical practice guidelines, such as those developed by the AARC, are not clinical indicators *per se*, but Guidelines developed by the AARC should be consistent with the JCAHO concept of clinical indicators. By establishing a peer-reviewed basis for the appropriate use of respiratory care, the AARC CPGs can be used as a component of a continuous quality improvement program. With increasing emphasis on outcomes, the CPGs can be used to determine whether the outcomes associated with respiratory care procedures are appropriate.

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A version of this editorial will be published in *International Anesthesiology Clinics* in 1996.

All clinical practice guidelines should improve the consistency and appropriateness of care, and serve as a guide for education and research. They should define and justify clinical practice.[5] This is important and necessary for the following reasons.

**Technology explosion:** Many respiratory care technologies exist that were not available 20 years ago; these include pulse oximetry, pressure support ventilation, and microprocessor ventilators, to name a few. The appropriate integration of such technologies into clinical practice is often unclear and should be aided by AARC CPGs—an example is the CPG on Pulse Oximetry. There are also changes in the application of existing therapies. Examples include oxygen therapy, aerosol therapy, IPPB, and incentive spirometry—for each of which there is now a related AARC CPG.

**Information explosion:** It is axiomatic that an information explosion exists in health care. For example, there were 8,663 articles related to 12 respiratory care topics from 1991 until mid-1995 (Table 1). It is impossible for anyone to read all of this literature, assess its scientific validity, and integrate its findings into everyday patient care.[27] Clinical practice guidelines should help to bridge the gap that often exists between academicians and clinicians. Each of the AARC CPGs is supported by an extensive bibliography. However, the CPGs are not intended to be a meta-analysis and are based upon consensus as well as science. This is particularly the case when the scientific basis may not be clear, but the practice is established and considered appropriate by respected clinicians.

Table 1. Number of Citations Identified from a MEDLINE Search of Twelve Respiratory-Care-Related Topics Published between 1991 and Mid-1995.

| Topic | Number of Citations |
|---|---|
| Pulse oximetry | 709 |
| Oxygen therapy | 591 |
| Arterial blood gases | 582 |
| Nebulizers, inhalers, & aerosol therapy | 332 |
| Mechanical ventilation | 2,069 |
| Suctioning | 158 |
| Cardiopulmonary resuscitation | 1,494 |
| Chest physiotherapy | 59 |
| Spirometry | 1,334 |
| IPPB & incentive spirometry | 57 |
| Indirect calorimetry | 630 |
| Humidifiers | 48 |
| **Total** | 8,663 |

**Physician, administrator, & patient expectations:** Physicians, hospital administrators, patients, and third-party payers sometimes have differing expectations of respiratory care practitioners. The clinical practice guidelines should improve the congruence of those expectations. There is increased interest in providing only those therapies for which there is a scientific basis, and the CPGs should provide this scientific basis or indicate when it is absent. CPGs should provide a basis for effective physician-therapist interactions.

**Regulation, litigation, & risk management:** CPGs should provide the basis for appropriate care. At the same time, they should be flexible enough to be tailored to the individual needs of specific patients. Although they are intended to be *guidelines*, they are likely to become accepted as *standards* of care. As such they may play an important role in malpractice claims and establishment of a standard of care.[28] The adoption of anesthesia guidelines has resulted in lower malpractice insurance premiums.[29,30] The role of respiratory care guidelines in risk management remains to be determined.

**Restructuring of respiratory care services:** Restructuring, re-engineering, and 'downsizing' are common 'buzz' words of the 1990s. Respiratory therapists, like all other health-care providers, are being asked to work smarter and more efficiently. There are increasing pressures to provide appropriate care with fewer respiratory therapists. This forces respiratory care departments to decrease the numbers of respiratory care procedures that are provided. The challenge is to eliminate unnecessary care while providing high-quality respiratory care when it is indicated. Managed care providers will demand appropriate allocation, and the responsibility for this will fall increasingly on the shoulders of respiratory therapists. The CPGs should provide assistance to respiratory care departments for developing triage mechanisms so that care is appropriately allocated.

**Respiratory care protocols:** To address the issue of misallocation, increasing numbers of respiratory care departments have worked with their medical staff to develop respiratory care protocols or respiratory care consult services. With such programs, physicians delegate patient-care decisions to respiratory therapists. The respiratory therapist is then responsible for patient assessment, delivery of the appropriate therapy, assessing the response to the therapy, and discontinuing the therapy when it is no longer indicated. Respiratory care protocols are likely to receive increasing clinical application, with fewer specialist physicians and fewer house staff in teaching hospitals. Many respiratory care departments have already used the CPGs to develop institution-specific respiratory care protocols.

**Outcomes and patient satisfaction:** There is increasing pressure to show that clinical interventions improve outcome. This focus on outcomes has been referred to as "the third revolution in medical care."[31] Although they are different, the terms guidelines and outcomes are often used in the same context. The origins of the outcomes movement are similar to those for guidelines development—cost containment and geographic

differences in practice.[32-34] In theory (yet unproven), implementation of well-constructed guidelines should improve the outcomes of health care. There is also increased interest in patient (and family) satisfaction with the quality of care provided. Implementation of CPGs should be consistent with the concept of patient-focused care. In the future, there will be increasing pressure on the health-care delivery system to provide only those therapies that improve quality, outcome, and patient satisfaction and simultaneously reduce cost. CPGs should provide measurable outcomes that can be used to assess respiratory therapy procedures.

### The AARC Clinical Practice Guidelines

The AARC's initiative to develop clinical practice guidelines formally began in 1990. The responsibility to develop Guidelines rests with the CPG Steering Committee. The Steering Committee oversees the activities of Working Groups who are directly responsible for drafting Guidelines. There have been Working Groups for oxygen therapy, aerosol therapy, mechanical ventilation, bronchial hygiene, cardiopulmonary diagnostics, cardiopulmonary resuscitation, and home respiratory care. These Working Groups consist of 4-8 individuals with expertise in the specific topic and include both respiratory therapists and physicians.

The process being used to develop the AARC CPGs is shown in Figure 1. The initial draft of each Guideline is developed from a thorough review of the literature, surveys of current practice, and the expertise of the members of the Working Groups. The initial draft of the Guideline then undergoes multiple revisions and editing by the Working Group, sometimes with the help of consultants to the Working Group. The Working Groups commonly spend hundreds of person-hours developing a single CPG. When the Working Group is satisfied with the Guideline, it is reviewed by the Steering Committee and distributed for peer review. The peer-review process typically involves over 500 individuals—respiratory therapists, physicians, and others. Every reviewer comment is considered by the Working Group that drafted the CPG and by the Chairman of the CPG Steering Committee. Following peer review and appropriate revision, the CPGs are published in Respiratory Care and widely distributed as reprints. From the beginning of the effort, it was anticipated that the Guidelines would be periodically revised and updated, and, in fact, that process has begun.

For the sake of consistency, each Guideline follows a similar structure:

- Procedure: Commonly used names for the procedure.
- Description: A short description of the procedure, written in the context of the Guideline.
- Setting: Specification of where it is appropriate to perform the procedure.
- Objectives/Indications: A list of the recognized objectives or indications for the procedure.
- Contraindications: Conditions that constitute absolute and relative contraindications to the procedure.
- Assessment of Need: A description of how the clinician determines that a procedure is indicated.
- Assessment of Outcome: A description of how the clinician should evaluate the benefit (or lack thereof) of a procedure.
- Resources: A description of the equipment and personnel required to perform the procedure.
- Monitoring: A description of what should be monitored during the procedure.
- Frequency: A statement regarding how frequently a procedure should be performed, or how one determines frequency.
- Infection-Control: Specific infection-control issues related to the procedure.
- References: The papers supporting the statements made in the Guideline.

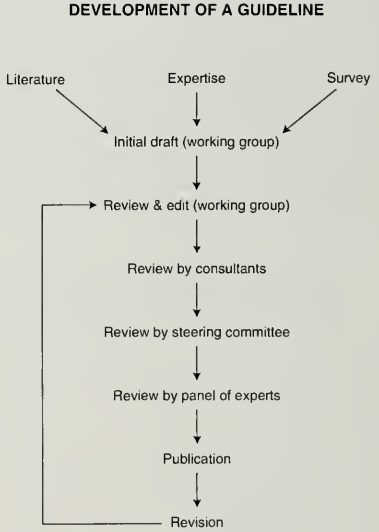


Fig. 1. Steps in the development of the AARC Clinical Practice Guidelines. (Reproduced from Reference 1, with permission.)

It is important that members of the respiratory care community hold appropriate expectations for CPGs (Table 2). Guidelines are not treatment protocols or critical pathways; they do not dictate staffing or salary levels; they do not set equipment budgets; and they do not seek to regulate institution-specific procedures. CPGs should, however, provide a broad,

but limited, context within which specific department procedures, policies, protocols, and critical pathways can be developed. In fact, institution-specific policies, procedures, and protocols could be constructed using the same format as the AARC CPGs.

Table 2. Appropriate Expectations of Clinical Practice Guidelines

| CPGs are: | CPGs are not: |
|---|---|
| Guidelines | Procedures |
| Clinical | Hypothetical |
| Practical | Theoretical |
| Brief statements | Lengthy reviews |
| Profession-oriented | Institution-oriented |
| Voluntary | Regulatory |
| Evolving | Static |

From Reference 1

The literature clearly indicates that clinical practice guidelines do not necessarily change practice.[35-38] If guidelines are to be adopted, they must be widely disseminated; they must be reasonable and readable; they must be consistent with acceptable practice; they must have wide review before publication; and they must be reviewed and updated periodically.

## The Future

Clinical practice guidelines will probably receive increasing attention throughout the 1990s. Guidelines are often considered in the context of health-care restructuring, cost containment, and appropriate allocation of care. The AARC is taking a leadership position in this movement. The development of AARC CPGs should be instrumental in improving the respiratory care administered to patients throughout the country. However, objective evaluation of the AARC CPGs, their use, and their impact on patient care has yet to be established. The Institute of Medicine has described desirable attributes of clinical practice guidelines (Table 3).[39] Conformance of the AARC CPGs to this description has not yet been independently evaluated. The AARC CPGs have been widely praised and translated into several languages. The CPGs have been credited as useful for the development of a respiratory care consultation program.[19,20,22,23] Their educational value has also been recognized, and they have been published in part or in whole in textbooks.[40-42] Although most observers have applauded the development of the AARC CPGs, their long-term impact on the delivery of respiratory care is yet to be determined.

Table 3. Desirable Attributes of Clinical Practice Guidelines

- validity
- reliability
- clinical applicability
- clinical flexibility
- clarity
- multi-disciplinary process
- scheduled review
- documentation

From Reference 39, with permission.

"Sometimes learning requires courage. It can be difficult for experts, especially, to admit that they could be better at what they do if only they knew more. To become a learner is to become vulnerable."

DM Berwick, 1991[43]

**Dean Hess PhD RRT**
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# Guidelines: A Call for Local Implementation and Assessment of Impact

The Clinical Practice Guideline: Polysomnography, published in this issue of RESPIRATORY CARE,[1] is a major step forward in recognizing the diversity of talent and skill needed to effectively diagnose and, thus, manage patients with sleep disorders. The two professional organizations—the American Association for Respiratory Care and the Association of Polysomnography Technologists—have outlined the necessary knowledge base and skills for "technicians" charged with constant attendance at sleep studies.[2] The career position that such technicians hold makes demands, requires specialized knowledge, and imposes responsibilities beyond those expected of many who perform 'routine' electrophysiology studies and respiratory care procedures. This document establishes a benchmark for that position.

The current 'guidelines approach' to medical and paramedical practice manifested as publications from professional societies and government agencies is a two-edged sword with inherent strengths and under-recognized weaknesses.[3,4] The need for guidelines is based upon the realization that considerable variation exists among cases and their management that are independent of patient outcome or satisfaction. The hope is that guidelines will capture the practices that lead to the best outcome and thereby reduce variations in care. All those involved would examine the literature and propose solutions. Often the solution might be to improve the system of care rather than to change physician behavior or training. Moreover, guidelines would incorporate recommendations designed to assess their impact—positive or negative—on the problem and to direct alterations over time (ie, provisions for continuous quality improvement).

General weaknesses should also be recognized. First, guidelines are easier to write than to implement or assess. Second, professionally derived guidelines can be too long, too detailed, and too specialized for general use. As a consequence, expressions of expert opinion or commercial 'pitches' may still have a greater impact.[5] Third, guidelines often do not identify, a priori, the end-users or would-be implementors—those in a position to directly improve care. Also, we have learned that local resources and resource allocation cannot be anticipated or dictated by national standards. In other words, there may be no one 'best' practice. Best practice may take a variety of forms.

So, how will this guideline fare? The problem: the need to define the equipment requirements and personnel skills involved in the diagnostic and therapeutic aspects of polysomnography. As a consequence of the publication of the guideline, I believe that the technical practice of polysomnography as a test or as part of a therapeutic trial is now better defined. And, in that regard I believe that the definition of the knowledge base is more important than the spelling out of procedural details. This document could easily be made a part of the procedure manual of those departments that manage patients with sleep disorders. However, I do hope that we avoid the "Wizard of Oz" mentality—a diploma rather than a brain—and focus on skills acquisition and assessment in functional terms, rather than by degree and credential acquisition.

Where can this guideline make the most impact? I encourage greater effort toward its local implementation and toward assessment of its local impact, rather than debate on the document per se. Sleep medicine is new; we have the opportunity to construct quality improvement procedures that acknowledge the validity of outcome measures addressing patient satisfaction, adherence to therapy, and improvement in the quality of life.[6,7] Do these guidelines affect care, satisfaction, or cost effectiveness? Are patients recovering faster? I encourage you to use this document to involve sleep-study personnel, physicians, and administrators in quality improvement over time. Five years from now, we should ask the question, Has this document improved care and access to care for patients? If it has, then it was worth the considerable "blood, sweat, and tears" that your organizations expended in putting it together.

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# Work of Breathing Imposed by Five Ventilators Used for Long-Term Support: The Effects of PEEP and Simulated Patient Demand

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**BACKGROUND: The imposed work of breathing ($WOB_I$) has been shown to be excessive during spontaneous breathing through home-care ventilators that have not been fitted with an H-valve and external continuous flow. Our goal was to determine whether the performance of a prototype ventilator similar in size to home-care ventilators and purported to be easy to use is comparable to the performance of a widely used intensive care ventilator. METHODS: We measured the $WOB_I$, maximum inspiratory pressure ($P_{Imax}$), delay time, and pressure-time product (PTP) during simulated spontaneous breathing via a lung model. We compared the Aequitron LP-6 and LP-10, PLV-102, Puritan-Bennett 7200ae, and Bird TBird VS ventilators. We also measured pressure-rise time and pressure overshoot during pressure support ventilation with the 7200ae and TBird VS. Data were collected from 6 simulated spontaneous breaths for each system at 3 levels of tidal volume and inspiratory flow (200 mL at 30 L/min, 400 mL at 60 L/min, and 600 mL at 90 L/min). RESULTS: The $WOB_I$, $P_{max}$, time delay, and PTP were greater with the 3 home-care ventilators than with the 7200ae or TBird VS. Additionally, as patient demand increased, all inferences of the $WOB_I$ increased. Performance of the TBird VS and of the 7200ae was similar although the TBird VS provided for a significantly lower $P_{Imax}$ and PTP while having a faster pressure-rise time during pressure support ventilation. CONCLUSION: Our results suggest that the $WOB_I$ during spontaneous breathing via home-care ventilators is excessive, and as a consequence the intermittent mandatory ventilation (IMV) modes should not be used without modification. The TBird VS and 7200ae ventilators are superior to the home-care ventilators and have a low $WOB_I$.** [Respir Care 1995;40(12):1270-1278]

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Abstracts based on the study reported here were presented by Mr Branson during the RESPIRATORY CARE OPEN FORUM at the 1995 Annual Meeting of the American Association for Respiratory Care held in Orlando, Florida, December 2-5, 1995.

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## Introduction

Mechanical ventilation of the patient in the intensive care unit (ICU) is costly.[1] Alternatives to ICU care include the care provided in step-down units, noninvasive-monitoring units, subacute-care facilities, and the home. Recent evidence suggests that subacute care may provide the most comprehensive care at the least expense.[2]

However, weaning patients in the subacute-care environment is a concern. In 1990, Kacmarek et al demonstrated the excessive work of breathing imposed ($WOB_I$) by home-care ventilators.[3] They suggested that these ventilators be used only in the assist/control mode or be modified with an H-valve system and

pass-over humidifier to allow intermittent mandatory ventilation (IMV) without excessive $WOB_I$. Because of the shortcomings of these ventilators, some subacute-care facilities use ICU ventilators. However, ICU ventilators tend to be more complex and less user-friendly and to limit patient mobility.

We evaluated 5 ventilators in the IMV mode (spontaneous breathing) and 2 ventilators in the pressure support (PSV) mode to compare the $WOB_I$, pressure-time product (PTP), maximum inspiratory pressure ($P_{Imax}$), and delay time.

The purpose of the study was to compare the $WOB_I$, PTP, and $P_{Imax}$ of 3 home-care ventilators, an ICU ventilator, and a prototype ventilator designed for subacute care similar in size to the home-care ventilators and purported to be simple to use. Our goal was to determine whether the prototype ventilator could demonstrate ICU performance.

## Materials & Methods

Five ventilators (1 of each model) were studied. Four of the ventilators were chosen because our research found that they were often used in subacute-care facilities. The fifth ventilator is a new device designed for subacute care. Included were 3 home-care ventilators (LP-6, LP-10, PLV-102),* an ICU ventilator (Puritan-Bennett 7200ae), and the prototype ventilator (TBird VS†). Table 1 provides a comparison of the modes, operational characteristics, physical characteristics, and manufacturers' suggested retail price.

### Ventilator Descriptions

**LP-6 and LP-10:** The LP-6 and LP-10 are electrically powered, electronically controlled volume-controllers that use a piston as the driving mechanism. Both operate in the control, assist/control, and IMV modes. Breaths are pressure-triggered and time- or volume-cycled. Spontaneous breathing occurs through the exhalation valve in the circuit, from within the ventilator via an antisuffocation valve, or through the air-intake valve of the piston chamber.

**TBird VS:** The TBird VS is an electrically powered, microprocessor-controlled, pressure- or volume-controller that uses a turbine as the driving mechanism. It operates in the control, assist/control, synchronized intermittent mandatory ventilation (SIMV), pressure support ventilation (PSV), and continuous positive airway pressure (CPAP) modes and can deliver pressure- or volume-limited breaths. Breaths are flow-triggered and can be time-, pressure-, flow-, or volume-cycled. Gas flow during spontaneous breathing is delivered via a drag turbine. During flow-triggering, the base flow is constant at 10 L/min and trigger sensitivity is adjustable from 2 to 9 L/min. After initiation of a breath, the TBird VS attempts to reach a pressure of 1.5 cm $H_2O$ above the set positive end-expiratory pressure (PEEP) or CPAP level. Inspiration is terminated when flow through the expiratory transducer becomes higher than 10 L/min.

* Suppliers of commercial products are listed in the Product Sources section at the end of the text.

† At the time of the study, the TBird VS had not received Food and Drug Administration approval.

Table 1. Operational Characteristics of the 5 Ventilators Studied

| Characteristic* | Aequitron LP-6 | Aequitron LP-10 | Bird TBird VS† | PLV-102 | Puritan-Bennett 7200ae |
|---|---|---|---|---|---|
| Modes | | | | | |
| CMV | √ | √ | √ | √ | √ |
| A/C | √ | √ | √ | √ | √ |
| SIMV | √ | √ | √ | √ | √ |
| PSV | — | — | √ | — | √ |
| CPAP | — | — | √ | — | √ |
| Output (range) | | | | | |
| Volume (mL) | 100-2,200 | 100-2,200 | 50-2,000 | 50-1,800 | 100-2,500 |
| Frequency (b/min) | 1-38 | 1-38 | 2-80 | 2-40 | 0.5-70 |
| PEEP (cm $H_2O$) | — | — | 0-30 | — | 0-45 |
| $F_{DO_2}$ | 0.21 | 0.21 | 0.21-1.0 | 0.21-1.0 | 0.21-1.0 |
| Pressure Limit (cm $H_2O$) | 25-100 | 25-100 | 20-130 | 5-95 | 10-120 |
| Air Source | Piston | Piston | Turbine | Piston | Compressor |
| Battery | √ | √ | √ | √ | — |
| Manufacturer's Suggested Price | $8,500 | $9,985 | $10,500† | $11,860 | $22,125 |
| Size | 9 × 14 × 13 | 9 × 13 × 12 | 12 × 12 × 11 | 9 × 12 × 12 | 40 × 22 × 26 |
| Weight (lb) | 34 | 32 | 28 | 28 | 328 |

*CMV = controlled mechanical ventilation; A/C = assist/control; SIMV = synchronized intermittent mechanical ventilation; PSV = pressure support ventilation; CPAP = continuous positive airway pressure; PEEP = positive end-expiratory pressure; $F_{DO_2}$ = fractional concentration of oxygen delivered.
† At the time of the study, the TBird VS was not yet approved by the Food & Drug Administration (510K application).

**PLV-102:** The PLV-102 is an electrically powered, electronically controlled volume-controller that uses a piston as the driving mechanism. It operates in the control, assist/control, and IMV modes. Breaths are pressure-triggered and time- or volume-cycled. Spontaneous breathing occurs through the exhalation valve in the circuit or through the air intake in the piston chamber.

**7200ae:** The 7200ae is an electrically powered, microprocessor-controlled, pressure- or volume-controller that uses gas from an air compressor and compressed oxygen as the driving mechanism and proportional solenoids for waveform output. It operates in the control, assist/control, SIMV, PSV, and CPAP modes. Breaths can be pressure- or flow-triggered and pressure-, flow-, or time-cycled. Gas flow during spontaneous breathing is provided via the proportional solenoids from the air and oxygen sources. During flow-triggering, the base flow is adjustable from 5 to 20 L/min and trigger sensitivity is adjustable from 1 to 10 L/min. After initiation of a breath, the TBird attempts to reach a pressure of 0.5 cm $H_2O$ above the set PEEP or CPAP level. Inspiration is terminated when flow through the expiratory flow transducer increases to 2 L/min above base flow.

### Experimental Set-Up

A patient model of simulated spontaneous breathing, similar to that originally described by Opt' Holt,[4] was used to evaluate the ventilators. A 2-chamber test lung was modified to allow the chambers to be connected by a lift bar. One chamber (driving chamber) was connected to a Bird VIP ventilator and the other (experimental chamber) was connected to the ventilators to be tested. When the driving chamber is ventilated by the ventilator, the experimental chamber is lifted by the lift bar, creating subatmospheric pressure in the experimental chamber. Our system used a metal T-piece attached to the experimental chamber, which was lifted by the driving chamber. A long metal screw was placed through the T-piece to allow communication between the 2 lungs even when PEEP was present in the experimental lung (Fig. 1). This obviated the need to add PEEP to the driving lung to balance chamber movement.

Compliance settings of the test lung were set at 0.04 L/cm $H_2O$ and resistance of the experimental chamber was created by a 8 3/16 in. length of endotracheal tube with a 7-mm internal diameter (ID) that provided a resistance of 5.9 cm $H_2O \cdot s \cdot L^{-1}$ at a flow of 1.0 L/s. The driving ventilator simulated spontaneous breathing, generating a sine-wave flow pattern and frequency of 10 breaths/min at 3 combinations of tidal volume ($V_T$) and peak inspiratory flow, or $\dot{V}_I$ (200 mL at 30 L/min, 400 mL at 60 L/min, and 600 mL at 90 L/min). All measurements were accomplished at 0 and 5 cm $H_2O$ PEEP. PEEP was created in the PLV-102, LP-6, and LP-10 using a disposable PEEP valve. The sine-wave flow pattern and volume-flow combinations were chosen to simulate breathing patterns from quiet to active that might be encountered in subacute care.

Only the 7200ae and TBird were studied during PSV. Measurements were made at 0 and 15 cm $H_2O$ PSV.

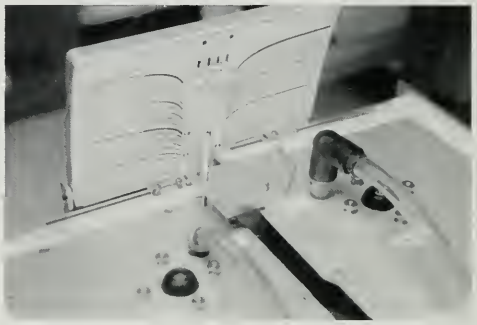

Fig. 1. Photograph showing screw that allows communication between the 2 lungs even when positive end-expiratory pressure is present in the experimental lung.

### Measurements

Pressure was measured at the proximal airway of the experimental chamber with a differential pressure transducer. Flow was derived from the pressure drop across the pneumotachograph measured at the proximal airway of the experimental chamber. Signals from the pressure transducers were amplified and integrated using a personal computer. Data acquisition was accomplished at a sampling period of 8 ms (frequency 125 Hz). All raw data were saved on the computer for subsequent retrieval and analysis. Pressure, flow, and volume were displayed using a recording oscilloscope.

Pressure and flow measurement systems were calibrated, across the range of measurement, between each series of tests with a U-tube water manometer and rotameter. WOB was calculated as the area subtended by the pressure-volume curve and expressed in J/L (Fig. 2). PTP was measured as the average airway pressure multiplied by the inspiratory time and expressed in cm $H_2O \cdot s$. Time delay was calculated as the time from the initial deflection of the airway pressure signal until the return of airway pressure to the baseline (Fig. 3). The $P_{Imax}$ was defined as the most negative pressure reading during a simulated inspiration.

During PSV, 2 additional measurements were made: the pressure-rise time and the pressure overshoot. Pressure-rise time was defined as the time from triggering until airway pressure reached 90% of the set PSV level of 15 cm $H_2O$. Overshoot was defined as the difference between actual peak airway pressure and the set level of pressure support (Fig. 3).

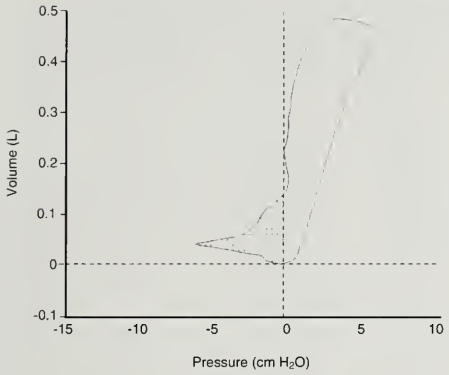


Fig. 2. Area of the pressure-volume curve used to calculate work of breathing in this study.

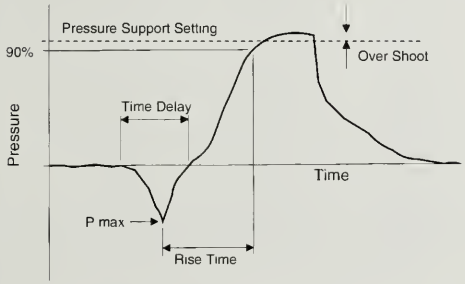


Fig. 3. A representative pressure support breath and the points of data collection.

All ventilators were set up according to manufacturers' specifications, and operational verification procedures were performed. The inspiratory limbs of the ventilator circuits were identical in length and included a dry, adult-size humidification chamber. The 3 home-care ventilators used an exhalation valve in the expiratory limb of the circuit, and the other 2 ventilators used an expiratory circuit connected to an internal exhalation valve. Trigger sensitivity was set at the maximum level (−1 cm $H_2O$) for all home-care ventilators. Because of system differences, only the 7200ae and TBird VS were tested during PSV. Both were tested using flow-triggering.

We collected data for 6 breaths at each experimental condition and calculated means and standard deviations. Statistical analysis was accomplished using commercially available software. Differences in variables among ventilators at a given condition were tested by 1-way analysis of variance (ANOVA), and differences for a given ventilator at different conditions was tested using 1-way ANOVA for repeated measures. The level of significance was set at $p < 0.05$.

## Results

Data comparing the 5 ventilators are shown in Table 2. Data for comparison of PSV between the 7200ae and TBird VS are shown in Table 3. Delay times based on our data but calculated according to the definition of Sassoon[7,21,22] are provided in Table 4. In the spontaneous breathing mode, the 7200ae and TBird VS provided a statistically significant lower WOB, delay time, $P_{Imax}$, and PTP at each simulated patient demand and PEEP level. The presence of PEEP resulted in significant increases in WOB, $P_{Imax}$, and PTP for the 3 home-care ventilators, but differences in variables for the TBird VS and 7200ae were not statistically significant.

As simulated patient demand (ie, $\dot{V}_I$) increased, all measured variables were statistically significantly greater than at the previous simulated demand for all ventilators (90 L/min > 60 L/min > 30 L/min).

At a simulated patient demand of 400 mL ($\dot{V}_I = 60$ L/min) and 600 mL ($\dot{V}_I = 90$ L/min), the $P_{Imax}$ and PTP were lower with the TBird VS than with the 7200ae ($p < 0.05$). However, WOB was not statistically different. Time delay was less with the TBird VS at a 600-mL volume, $\dot{V}_I$ of 90 L/min, and PEEP of 5 cm $H_2O$ than with the 7200ae [0.26 (0.01) vs 0.36 (0.3), $p < 0.05$].

During PSV, the TBird VS had a statistically significant lower $P_{Imax}$, WOB, PTP, and delay time than the 7200ae ($p < 0.01$). Pressure-rise time was faster with the TBird VS at the 2 lower patient demands ($V_T = 200$ mL, $\dot{V}_I = 300$ L/min, and $V_T = 400$ mL, $\dot{V}_I = 60$ L/min) than the 7200ae, but there was no statistically significant difference at the highest patient demand. Overshoot was approximately 40% less with the TBird VS than with the 7200ae at all simulated patient-demand settings. Pressure-volume curves for the 5 ventilators at a PEEP of 5 cm $H_2O$ and at $V_T$ of 600 mL with an $\dot{V}_I$ of 90 L/min are shown in Figure 4 for comparison.

Figure 5 shows pressure support of 15 cm $H_2O$ delivered by the 7200ae and TBird VS with a simulated patient demand of 400 mL and $\dot{V}_I$ of 60 L/min.

## Discussion

Our results confirm the findings of Kacmarek et al,[3] demonstrating high $WOB_I$ and excessive $P_{Imax}$ during simulated spontaneous breathing through home-care ventilators. Our study suggests that the LP-10 is superior to both the LP-6 and PLV-102 with regard to WOB, PTP, and $P_{Imax}$. We also present data confirming the adverse effect of PEEP on WOB with these ventilators.

Our results also demonstrate that the prototype ventilator tested, the TBird VS, performs comparably to the Puritan-Bennett 7200ae in both the CPAP and PSV modes. This

Table 2. Comparison of Measured Variables at Various Tidal Volumes ($V_T$s) and Inspiratory Flows ($\dot{V}_I$s), at Frequency of 10 Breaths/Min*

| Ventilator | PEEP (cm $H_2O$) | Delay Time (s) | $P_{Imax}$ (cm $H_2O$) | WOB (J/L) | PTP (cm $H_2O \cdot s$) |
|---|---|---|---|---|---|
| $V_T$ = 200 mL & $\dot{V}_I$ = 30 L/min | | | | | |
| Aequitron LP-6 | 0 | 0.60 (0.01) | −2.7 (0.05) | 0.13 (0.001) | 0.98 (0.007) |
| | 5 | 0.63 (0.01) | −7.5 (0.06) | 0.30 (0.003) | 3.50 (0.06) |
| Aequitron LP-10 | 0 | 0.52 (0.01) | −1.8 (0.08) | 0.09 (0.003) | 0.63 (0.04) |
| | 5 | 0.62 (0.01) | −6.7 (0.04) | 0.26 (0.001) | 3.10 (0.03) |
| TBird VS† | 0 | 0.10 (0.005) | −1.0 (0.3) | 0.005 (0.001)‡ | 0.06 (0.009)‡ |
| | 5 | 0.15 (0.01) | −1.4 (0.16) | 0.007 (0.001) | 0.09 (0.007) |
| PLV-102 | 0 | 0.61 (0.03) | −2.9 (0.05) | 0.14 (0.001) | 1.0 (0.006) |
| | 5 | 0.63 (0.006) | −8.2 (0.1) | 0.32 (0.004) | 3.7 (0.07) |
| Puritan-Bennett 7200ae† | 0 | 0.15 (0.07) | −1.5 (0.08) | 0.012 (0.01) | 0.11 (0.08) |
| | 5 | 0.15 (0.02) | −1.7 (0.08) | 0.008 (0.001) | 0.11 (0.01) |
| $V_T$ = 400 mL & $\dot{V}_I$ = 60 L/min | | | | | |
| Aequitron LP-6 | 0 | 0.63 (0.01) | −5.9 (0.01) | 0.30 (0.001) | 2.3 (0.01) |
| | 5 | 0.65 (0.01) | −10.4 (0.07) | 0.54 (0.004) | 4.9 (0.05) |
| Aequitron LP-10 | 0 | 0.57 (0.01) | −3.8 (0.06) | 0.19 (0.002) | 1.5 (0.02) |
| | 5 | 0.64 (0.01) | −8.6 (0.04) | 0.45 (0.002) | 4.2 (0.03) |
| TBird VS† | 0 | 0.23 (0.02)‡ | −1.6 (0.4)‡ | 0.012 (0.002)‡ | 0.13 (0.02)‡ |
| | 5 | 0.18 (0.01) | −1.9 (0.1) | 0.007 (0.001)‡ | 0.12 (0.01)‡ |
| PLV-102 | 0 | 0.63 (0.01) | −6.7 (0.04) | 0.35 (0.003) | 2.6 (0.02) |
| | 5 | 0.65 (0.004) | −11.6 (0.07) | 0.58 (0.005) | 5.5 (0.06) |
| Puritan-Bennett 7200ae† | 0 | 0.46 (0.06) | −3.6 (1.3) | 0.07 (0.02) | 0.60 (0.06) |
| | 5 | 0.19 (0.01) | −2.6 (0.3) | 0.02 (0.002) | 0.21 (0.05) |
| $V_T$ = 600 mL & $\dot{V}_I$ = 90 L/min | | | | | |
| Aequitron LP-6 | 0 | 0.63 (0.007) | −9.3 (0.05) | 0.48 (0.002) | 3.7 (0.01) |
| | 5 | 0.64 (0.007) | −13.6 (0.06) | 0.72 (0.001) | 6.3 (0.02) |
| Aequitron LP-10 | 0 | 0.59 (0.001) | −6.5 (0.04) | 0.33 (0.001) | 2.5 (0.001) |
| | 5 | 0.64 (0.001) | −11.1 (0.07) | 0.58 (0.002) | 5.2 (0.04) |
| TBird VS† | 0 | 0.29 (0.01) | −1.9 (0.4)‡ | 0.03 (0.001) | 0.26 (0.02)‡ |
| | 5 | 0.26 (0.01)‡ | −2.4 (0.13) | 0.02 (0.001) | 0.22 (0.01)‡ |
| PLV-102 | 0 | 0.63 (0.009) | −11.2 (0.04) | 0.57 (0.001) | 4.4 (0.01) |
| | 5 | 0.64 (0.004) | −15.6 (0.1) | 0.79 (0.006) | 7.1 (0.1) |
| Puritan-Bennett 7200ae† | 0 | 0.26 (0.05) | −4.5 (2.2) | 0.04 (0.01) | 0.44 (0.15) |
| | 5 | 0.36 (0.3) | −2.8 (0.5) | 0.03 (0.005) | 0.35 (0.05) |

* Measured values are reported as mean (SD); PEEP = extrinsic positive end-expiratory pressure; $P_{Imax}$ = maximum negative inspiratory pressure; WOB = work of breathing; and PTP = pressure-time product.

† All values are statistically significant compared to LP-6, LP-10, PLV-102 ($p < 0.001$).

‡ Statistically significant compared to 7200ae ($p < 0.01$).

Table 3. Comparison of Variables during PSV (15 cm $H_2O$) as Provided by the 7200ae and TBird VS Ventilators

| Ventilator | $V_T$* (mL) | $\dot{V}_I$ (L/min) | Delay Time (s) | $P_{Imax}$ (cm $H_2O$) | WOB (J/L) | PTP (cm $H_2O \cdot s$) | Rise Time (s) | Overshoot (cm $H_2O$) |
|---|---|---|---|---|---|---|---|---|
| TBird VS | 200 | 30 | 0.08 (0.02)† | 0.6 (0.1)† | 0.002 (0.001)† | 0.02 (0.008)† | 0.23 (0.01)† | 0.46 (0.04)† |
| 7200ae | 200 | 30 | 0.14 (0.01) | 2.8 (0.3) | 0.010 (0.001) | 0.12 (0.02) | 0.36 (0.03) | 0.93 (0.03) |
| TBird VS | 400 | 60 | 0.09 (0.02)† | 1.0 (0.2)† | 0.004 (0.001)† | 0.03 (0.014)† | 0.21 (0.006)† | 0.57 (0.06)† |
| 7200ae | 400 | 60 | 0.12 (0.02) | 3.6 (0.5) | 0.020 (0.006) | 0.15 (0.03) | 0.34 (0.01) | 0.92 (0.04) |
| TBird VS | 600 | 90 | 0.07 (0.006)† | 1.5 (0.44)† | 0.007 (0.002)† | 0.05 (0.01)† | 0.43 (0.01) | 0.44 (0.06)† |
| 7200ae | 600 | 90 | 0.13 (0.02) | 4.0 (0.4) | 0.02 (0.007) | 0.17 (0.04) | 0.42 (0.01) | 1.80 (0.22) |

* Measured values are reported as mean (SD); $V_T$ = tidal volume; $\dot{V}_I$ = peak inspiratory flow; $P_{max}$ = maximum inspiratory pressure; WOB = work of breathing; and PTP = pressure time product.

† $p < 0.05$ vs 7200ae.

Table 4. Comparison of Delay Times in Puritan-Bennett 7200ae and TBird VS as Calculated by Method of Sassoon et al[7,21,22]

| Ventilator Settings (cm $H_2O$) CPAP/PEEP | PSV | Delay Time (ms) 7200ae | TBird VS |
|---|---|---|---|
| 5 | 0 | 89 ± 15 | 81 ± 10 |
| 0 | 15 | 72 ± 5 | 51 ± 10 |
| 0 | 0 | 96 ± 15 | 64 ± 7 |

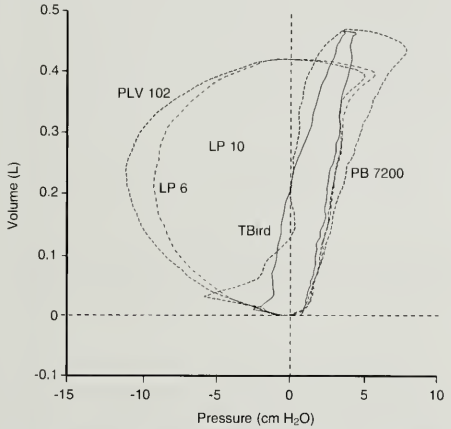


Fig. 4. Comparison of pressure-volume loops from the 5 ventilators used in the study at a simulated breathing effort of tidal volume = 400 mL and peak inspiratory flow = $\dot{V}_I$ of 60 L/min at 0 PEEP.

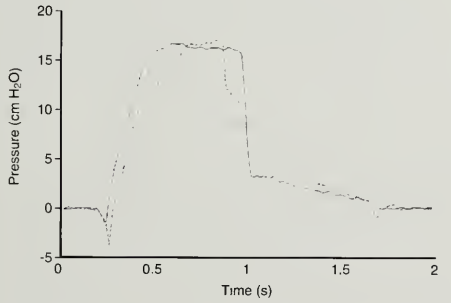


Fig. 5. Comparison of pressure-time curves for the TBird VS (—) and 7200ae (--) at 15 cm $H_2O$ PSV. Simulated patient effort is a tidal volume = 400 mL and peak inspiratory flow = 60 L/min.

new ventilator is intended for subacute and home care. A ventilator that combines compact size with ICU ventilator performance at a price similar to that of other home-care ventilators may represent an important advantage in the current health-care environment. Hirsch et al[5] found that the 7200ae compared favorably to other ICU ventilators during CPAP and PSV in a bench study of the $WOB_I$. We chose the 7200ae for our study because of its popularity and level of performance in other studies.[6-10]

The study findings are not unanticipated. All home-care ventilators studied allow spontaneous breathing via the exhalation valve, via the air intake of the piston, or via an anti-suffocation valve downstream from the piston. These systems, unless modified, by definition do not provide IMV but do allow spontaneous breathing of ambient air between mandatory breaths.[10] None of the home-care ventilators provides gas flow for spontaneous breathing unless modified with an H-valve system and external continuous flow. However, our experience suggests that these ventilators are used in the IMV mode without modification in both subacute and home care.

Adding PEEP to the expiratory valve of a home-care ventilator further increases the inspiratory workload. This also complicates spontaneous breathing because the PEEP valve typically allows only unidirectional flow, eliminating the exhalation valve as a source of ambient air. With these 3 ventilators, the use of extrinsic PEEP creates a spontaneous (auto-PEEP) or expiratory positive airway pressure (EPAP) system,[11] which requires the patient to overcome circuit pressure prior to receiving gas flow. In our experiment, a pressure reduction of 5 cm $H_2O$ was required to allow entrainment of air into the circuit. This type of system is associated with a further increase in the WOB.[12,13]

Numerous studies have evaluated the WOB imposed by current ICU ventilators.[6-10,14-17] These reports show the $WOB_I$ of ICU ventilators to be small (< 0.09 J/L). Our results using the TBird VS and 7200ae also demonstrate a low WOB (< 0.04 J/L), as little as one tenth of that seen with the 3 home-care ventilators (Table 2). The clinical importance of these differences is unclear. In many instances, one ventilator may have a WOB equivalent to half of that of another ventilator (0.08 to 0.04 J/L), yet the total effect on patient WOB may be negligible. If we assume normal WOB to be 0.5 J/L, a decrease in the imposed work of 0.04 J/L represents only an 8% decrease in total patient work. This does not suggest that the work to trigger is unimportant. Gurevitch and Gelmont[18] have shown that excessive $WOB_I$ can cause dyssynchrony and air hunger. However, clinicians should analyze the claims of manufacturers who cite the scientific literature and should understand the true meaning of a 50% reduction in the $WOB_I$.

Comparing our results to other studies is difficult. The type of ventilator circuit used, humidifier, test lung, and simulated patient effort (volume, flow, and flow pattern) are frequently different.[5,7,8,14-17] Kacmarek et al[3] found that the least $WOB_I$ in home-care ventilators was associated with a pass-over humidifier, followed by a heat and moisture exchanger and bubble humidifier. We used the same pass-over wick humidifier and identical lengths of inspiratory tubing in all cases. The 3 home-care ventilators use a mushroom-type exhalation valve; whereas, the TBird VS and 7200ae have built-in exhalation

valves. This necessitates using a longer expiratory tube with these 2 ventilators.

Banner et al[19,20] have suggested that inspiratory WOB can be affected by the exhalation valve. We used the exhalation valve provided by the manufacturer and the same PEEP valve for each home-care ventilator. It is possible that the increase in WOB with the PLV-102 is partially attributable to the exhalation valve, but we did not measure this specifically. Internal exhalation valves used by the 7200ae and TBird VS may also contribute to the lower WOB with these ventilators, but the major difference remains the demand flow system.

Considerable work on flow-triggering has been reported recently by a number of investigators.[6-9,14-17,21-22] The consensus appears to be that flow-triggering reduces response time by approximately 25% compared to pressure-triggering.[21,22] This may be due to the presence of continuous flow, the position of the exhalation valve (open during flow-triggering, closed during pressure-triggering), and a shorter time delay.[21,22] However, as initially pointed out by Sassoon et al[7] and our group,[6,9] the differences in flow- and pressure-triggering with the 7200ae are due to changes in the limit variable. During pressure-triggering, the ventilator is designed to maintain circuit pressure at the PEEP level minus the sensitivity setting and to maintain a circuit pressure 1.0 to 2.0 cm $H_2O$ above PEEP during flow-triggering. The result is a more rapid 'attack' of flow during flow-triggering and a small amount of pressure support.

Because the TBird VS uses flow-triggering exclusively, we compared the 7200ae and TBird VS only during flow-triggering. The TBird used a base flow of 10 L/min and flow sensitivity of 2 L/min. The 7200ae was set at a base flow of 6 L/min and flow sensitivity of 2 L/min. At each simulated patient demand, the TBird VS demonstrated a smaller $P_{Imax}$, lower WOB, and lower PTP than did the 7200ae. These differences were small and probably do not represent a clinically important difference. In many instances, the two ventilators appeared to perform identically (Fig. 6). Because only one of each ventilator was studied, some of the differences seen could be specific to that individual ventilator. Beydon et al[23] found that a group of 20 Ohmeda CPU-1 ventilators showed significant differences in performance unrelated to the age of the machines. Our study design is limited by the use of a single unit of each ventilator model, and this may help to further explain the differences in published results.

Unlike results of previous studies, we did not see significant differences in WOB with the addition of PEEP to the two microprocessor ventilators. This may be due to our method of connecting the lung model chambers. When PEEP is added to the experimental chamber, PEEP is typically added to the driving chamber to prevent the shock wave seen when one chamber 'hits' the other. Our system allowed the driving chamber to remain at a baseline of 0 cm $H_2O$ by adjustment of the screw to allow the chambers constant communication (Fig. 1). We believe the addition of PEEP to the driving chamber might cause an increase in measured work due to a change in test lung compliance as the spring is stretched. We emphasize that comparison of individual studies is inherently difficult because of the number of potential confounders. We believe that each individual study should be judged as a comparison of the particular devices studied at the conditions present in the study.

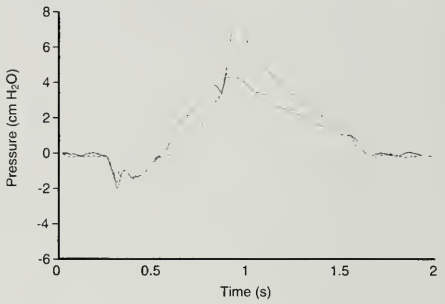


Fig. 6. Pressure-time curves during spontaneous breathing using the 7200ae (--) and TBird VS(—). Simulated patient effort is a tidal volume = 400 mL and peak inspiratory flow = 60 L/min.

Aside from the typical measures of WOB and $P_{Imax}$, we also evaluated time delay and PTP. Our definition of time delay is shown in Figure 3. This definition differs from that used by Sassoon et al[7,21,22] but we believe it to be more relevant. Our time delay includes the work to trigger the ventilator as well as the response to the patient effort (return of pressure to baseline). Sassoon et al defined time delay as the time between initial effort and response of the ventilator. (Values obtained from our data but calculated according to Sassoon et al's definition are given in Table 4.) As Sassoon has pointed out, ventilator response following triggering is as important or more important than the initial $P_{Imax}$. Our results suggest that the trigger delay of the TBird is 10 to 20 ms less than that of the 7200ae. The importance of these differences in adult patients with respiratory frequencies of 10 to 25 breaths/min is unclear. Time delay is a comparison of how rapidly a ventilator responds to patient demand. Care should be used that definitions of time delay in subsequent studies are similar. PTP accounts for the work prior to initiation of flow to be quantified. In many cases, a ventilator may have a low WOB because the limit variable is greater than the baseline pressure. In fact, it is possible for a ventilator with a $P_{Imax}$ of −6 cm $H_2O$ to have a lower WOB than a ventilator with a $P_{Imax}$ of −3 cm $H_2O$ if the attack rate is faster and 2-3 cm $H_2O$ pressure support are delivered.[24] PTP includes the amount of patient effort required to trigger the ventilator prior to initiation of flow.

Hirsch et al[5] compared ICU ventilators during PSV and found a wide range of imposed work of breathing values (0.02-0.0002 J/L). They also measured delivered $V_T$, inspiratory

time, and peak $\dot{V}_I$. Our comparison of the 7200ae and TBird VS evaluated WOB, $P_{Imax}$, PTP, delay time, rise time and overshoot. We chose the latter 2 variables as a method of determining adequacy of the control algorithms of the 2 ventilators. The 90% rise time reflects how quickly the pressure support level is reached, and this has been associated with the lowest $WOB_I$ in lung model studies.[25] The overshoot is a measure of the ability of the ventilator servo-control system to maintain the desired airway pressure.

Our results show that, for the most part, the 7200ae and TBird VS have comparable performance during PSV. However, the TBird VS that we tested had a significantly lower $P_{Imax}$ and PTP and a shorter delay time. The pressure-rise time was approximately 30% faster with the TBird VS at the first 2 simulated conditions (200 mL at 30 L/min, 400 mL at 60 L/min) but equivalent at the 600 mL and 90 L/min setting. This may be due to a change in the attack rate of the 7200ae as demand is increased. The differences in the WOB were also statistically significant although the clinical importance of these small values (0.004 vs 0.02 J/L) is unclear. Overshoot was greatest with the 7200ae when simulated patient demand was greatest (Table 3). At the other 2 conditions, both ventilators demonstrated an overshoot < 1 cm $H_2O$. The clinical importance of overshoot is uncertain, and these evaluations are simply comparisons of the 2 ventilators under similar conditions.

A current trend in mechanical ventilation is to transfer patients from the hospital to subacute or home care. Our experience suggests that a factor limiting or complicating this transition is the inability of current home-care ventilators to provide IMV and PSV and to allow spontaneous breathing at a reasonable $WOB_I$. Use of sophisticated ICU ventilators solves this problem but sacrifices cost, portability, and size (Table 1). Our current search for a product which combines ICU performance with lower cost and portability led to the performance of this study.

## Summary

We have confirmed the results of Kacmarek et al[3] concerning the high $WOB_I$ associated with current home-care ventilators. We concur with their conclusion that these systems should not be used to provide IMV without an H-valve system. Of note is the lower $WOB_I$ associated with the LP-10, a ventilator not available at the time of the Kacmarek study. This suggests some effort has been expended reducing the $WOB_I$ since the initial report.

Our evaluation shows the superiority of the TBird VS and 7200ae ventilators over the home-care units. There are measurable differences in the performance of the TBird VS and 7200ae, although the clinical impact of these differences is speculative. Our overall impression is that the function of the TBird VS with respect to the measured variables may be slightly better than the 7200ae. The TBird ventilator has the advantage of being portable and operating from a low-flow oxygen source—two desirable characteristics.

### PRODUCT SOURCES

**Ventilators & Ancillary Equipment:**

Aequitron LP-6 and LP-10, Aequitron Medical, Minneapolis MN
TBird, Bird Products Corporation, Palm Springs CA
Lifecare PLV-102, Lifecare Corp, Boulder CO
Puritan-Bennett 7200ae, Puritan-Bennett Corporation, Carlsbad CA
Humidification Chamber, Fisher & Paykel, Auckland, New Zealand

**Testing, Recording, & Calculating Equipment:**

Fleisch Pneumotachograph, Switzerland
Differential Pressure Transducer, MP45-1871, DP45-32, Validyne Engineering Corp, Northridge CA
Signal Conditioners & Carrier Demodulators, Validyne Engineering Corp, Northridge CA
METLAB Software, MathWorks Inc, Natick MA
486DX 33-mHz computer, New Edge Systems
Data-acquisition card, Keithley DAS 16, Taunton MA
Test Lung, TTL, Michigan Instruments MI

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# Airway Management of the Chronically Intubated Patient

George S Leisure MD, David J Stone MD, Burkhard F Spiekermann MD, and David L Bogdonoff MD

**Introduction**
**Oral vs Nasal Long-Term Endotracheal Intubation**
**Apparent Endotracheal-Tube-Cuff Leaks**
**Endotracheal Tube Size**
**Changing the Endotracheal Tube**
**Laryngotracheal Injury from Endotracheal Intubation**
**Extubation**
**In Conclusion**

## Introduction

Optimal care of adult patients requiring chronic endotracheal intubation demands a thorough knowledge of airway problems—problems that are different from those encountered in acute airway management. In this review, we address some of the more important considerations facing the clinician in the maintenance of the chronically intubated patient (ie, one intubated for longer than 72 hours). Skillful and meticulous daily care of the upper airway should decrease the risk of complications related to translaryngeal intubation.

## Oral vs Nasal Long-Term Endotracheal Intubation

The considerations for long-term oral versus nasal endotracheal intubation are outlined in Table 1. Although all of these factors must be appreciated, the concerns over stability and sinusitis deserve the most attention. Although nasal endotracheal tubes (ETTs) are often believed to be better tolerated, a study of prolonged intubation revealed that comfort was not a distinguishing factor between the two routes.[1] Adequate airway suctioning can be accomplished with the ETT in either location but may be more difficult through a nasal ETT, possibly due to the tube's size or angle of curvature. Oral hygiene is more easily maintained with a nasal ETT. In nasally intubated patients, dental trauma may be avoided by circumventing the use of a bite block or oral airway intended to prevent the patient from biting down on and occluding the ETT. Aerophagia in the nasally intubated patient can become

Table 1. Comparison of Advantages and Disadvantages of Oral and Nasal Intubation

| | Oral | Nasal |
|---|---|---|
| Stability | ± | +? |
| Sinusitis | + | – |
| Oral hygiene | – | + |
| Lack of bite block requirement | – | + |
| Pressure necrosis of adjacent tissue | – | – |
| Comfort | ± | ± |
| Suctioning | ± | ± |
| Ability to use larger tube | + | – |
| Laryngeal damage | – | +? |

\+ Clear advantage
+? Possible advantage
– Disadvantage
± Indeterminate

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clinically important, leading to severe gastric distention. Tissue compression by either a nasal or oral ETT can cause pressure necrosis of the alae nasi or lips within hours. The resultant defect may be distressing to the patient and family and be difficult to repair. Appropriate ETT size is addressed in detail in a later section, but let us say here that the nasal route may require a smaller ETT than can be inserted orally. The use of smaller ETTs may contribute to the lower incidence and degree of laryngeal damage associated with nasal intubation, but other factors may also play a role. For example, because nasally placed ETTs may be somewhat more stable than orally placed ones, they may be responsible for less movement-related injury to the larynx. Furthermore, a nasally placed ETT may enter the larynx in a straighter position than one placed orally and, thereby, cause less damage to the larynx.[2]

The issue of stability of the ETT is important because reintubation can be associated with significant morbidity and the potential exists for complete loss of the airway. Premature extubation can occur from movement of the patient's head, movement of the ETT by the patient's tongue, traction on an ETT connected to a ventilator circuit, routine ETT care, repositioning of the patient, or self-extubation. It is interesting to note that at least one study has shown that many patients who extubate themselves do not require reintubation.[3] Although nasal tubes are believed to be more stable, Coppolo and May[3] found no significant difference in the incidence of unintended extubation between patients who were intubated orally or nasally. In contrast, a study by Bach et al[4] revealed a higher incidence of unintended extubation and mainstem intubation with subsequent atelectasis in orotracheally intubated patients. In either case, the ETT should be carefully secured and meticulous attention paid to care of the skin.

Finally, paranasal sinusitis is a well described complication of nasotracheal intubation.[5-8] The immunocompromised patient and the head-injured patient with blood in the sinuses may be at higher risk of developing clinically important sinusitis. After 5 days of nasal intubation, the risk of sinusitis increases dramatically.[6] In one study, the incidence of sinusitis in nasotracheally intubated patients was 43% versus 1.8% in the orotracheally intubated group.[7] Furthermore, nasotracheal intubation has been associated not only with a higher incidence of maxillary sinusitis but also with more extensive disease, with infection spreading to frontal, ethmoidal, and sphenoidal sinuses.[4] Michelson et al[8] have reported that, in nasally intubated patients, the incidence of bilateral sinusitis is significantly higher and its onset earlier. The mechanism of sinusitis development may relate to injury to the sinus ostia induced by nasal tube insertion, resulting in edema and subsequent mechanical obstruction of the ostia. However, the findings of one study stand in contrast to these findings. Holzapfel et al[9] found no statistically significant difference in the occurrence rate of nosocomial sinusitis in nasally versus orally intubated patients. He and his collegues did find a trend that suggested less sinusitis in those with oral tubes. Diagnosis of severe sinusitis is probably best made by computerized tomography (CT), especially in cases of sphenoid or pansinusitis. However, fever and purulent discharge in combination with bedside radiography (Water's view) or ultrasound may be sufficient to establish the diagnosis.

Treatment of severe sinusitis must be instituted promptly because of the potential for sepsis and serious intracranial infection. When severe sinusitis is suspected, one should remove all tubes from the nasal passages including nasogastric (NG) tubes, institute broad spectrum antibiotics, and initiate a course of oxymetazoline HCl. If these measures fail or in cases of pansinusitis or life-threatening sepsis, drainage is recommended. As a result of the serious nature of sinusitis and the possibly higher risk of sinusitis in the nasotracheally intubated patient, orotracheal intubation may be more desirable for long-term care.

### Apparent Endotracheal-Tube-Cuff Leaks

Air leak around an endotracheal tube is a common problem in patients requiring mechanical ventilation. Stauffer et al[1] noted an 11% incidence in their study of 226 intubations in 150 patients. Rashkin and Davis[10] noted an air leak in 15 of 61 patients during a study of acute complications of endotracheal intubation, and 12 of these 15 patients required reintubation. Small leaks may be simply an annoyance and may not constitute an emergency. However, leaks can impair adequate ventilation and place the patient at risk for aspiration of gastric contents. The causes of apparent cuff leaks are summarized in Table 2.

Table 2. Factors Giving Rise to Inability To Provide Leak-Free Ventilation

| |
|---|
| Incorrect cuff position |
| Tube size too small |
| Leak in balloon/valve system |
| True cuff leak |
| Tracheomalacia |
| Tracheoesophageal fistula |

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The most frequent cause of leaks around the cuff is incorrect positioning of the ETT. In a study by Kearl and Hooper[11] to determine the abnormalities present in ETTs removed due to "massive air leak," they found that 61% of those tubes had no mechanical fault. They concluded that tube malposition caused the leaks. In general, oral ETTs are properly positioned at 23 cm at the upper teeth in men and at 21 cm in women (Fig. 1).[2] For nasally placed tubes, approximately 3 cm of additional distance is needed for proper positioning. These depths of insertion usually place the tube cuff sufficiently below the vocal cords and yet make endobronchial intubation unlikely. However, unusually tall or short persons may require adjustments

based on bronchoscopic or radiographic location of the tube. A leak is likely to develop if the cuff protrudes above the vocal cords, and large cuff volumes may be required to seal the airway. Laryngoscopic examination or even visual inspection of the oropharynx usually identifies this condition.

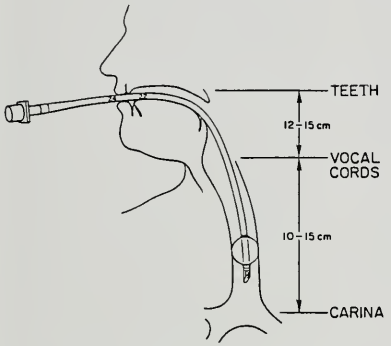


Fig. 1. Diagrammatic representation of key distances related to positioning of the endotracheal tube. (Reprinted from Reference 2, with permission.)

Once proper position is achieved, it is essential to document the distance to the upper teeth or gums as indicated by the markings on the ETT. This may be difficult because the tape used to secure the tube may hide these markings. One method suggested to overcome this problem is to use a tongue blade to measure the distance either from the upper gums, the top front teeth, or the external nares to the proximal end of the ETT adapter, once correct position has been confirmed. The distance is marked on the tongue blade, and this measurement is used periodically to ensure correct tube positioning.[12]

Leaks due to inappropriately small ETTs are uncommon in adults, but they can occur. Patients with tracheobronchomegaly or emphysematous patients with large, compliant airways may require a larger ETT. The highly compliant airways found in emphysematous patients enlarge to a greater extent than do normal airways in the presence of positive pressure.[2] Furthermore, in a model of the trachea, it has been shown that higher intracuff pressures are required to maintain an airway seal in the face of high peak-inspiratory pressures in patients with decreased lung compliance.[13] This phenomenon may account for some leaks, especially in patients with smaller ETTs.

Airway leaks due to defects in either the pilot valve-balloon apparatus or cuff are less likely than leaks due to tube malposition. In the study by Kearl and Hooper,[11] it was found that pilot-valve problems occurred in 11% of tubes, and cuff defects were present in 28%. True leaks of the ETT cuff are usually detected immediately after intubation and generally are due to tears caused by the teeth, nasal turbinates, or Magill forceps. Cuff perforations occur more frequently in nasally placed ETTs. A leak due to cuff perforation should be suspected when the normal resistance to complete cuff inflation is lost. In addition, with the loss of cuff integrity, the increased resistance felt upon complete cuff deflation is also lost. In these cases, the cuff may not be seen on chest radiograph and may not be palpable in the suprasternal notch. The use of a continuous flow device to maintain inflation of a leaking cuff has been described and could be used as a temporary measure.[14] Late occurring leaks are more common in the pilot-valve apparatus than in the cuff. In the case of a valve leak, a 3-way stopcock or T-connector can be placed to maintain a seal. If the valve housing or balloon is disrupted, the connecting tubing can be cut and an alcohol-lubricated 22-gauge angiocatheter inserted into the tubing, the stopcock reconnected, and the seal verified.

Finally, physical abnormalities of the airway or structural complications of intubation can cause leaks. Tracheomalacia, tracheal diverticula, tracheal cysts or tumors, and tracheoesophageal fistula may all result in difficulty sealing the airway. In the case of tracheomalacia, the ETT can be advanced to a different site in the trachea to achieve an adequate seal or simply be replaced with a larger tube. An ETT with a large, low-pressure foam-filled cuff introduced by Kamen and Wilkinson (Bivona Surgical, Hammond IN) may help in this situation. A cuff seal is not necessary if the patient can be successfully ventilated with some form of high-frequency jet ventilation, which provides high flows and, thus, decreases the leak. However, the airway will not be protected from aspiration of secretions or gastric contents.

### Endotracheal Tube Size

We have already addressed the contribution of ETT size to the development of airway leaks, and we now focus on 3 other common considerations with respect to ETT size: fiberoptic bronchoscopy, weaning from mechanical ventilation, and inadvertent or intrinsic positive end-expiratory pressure (auto-PEEP).

Meeting the ETT-size requirement for bronchoscopy is a common clinical problem. Bronchoscopists generally prefer an ETT with an internal diameter (ID) larger than 7.0 mm. When an adult flexible bronchoscope with a 4.9-mm outer diameter (OD) is placed into a 7.0-mm ETT, a cross-sectional area equivalent only to a 5.0-mm ID ETT remains for ventilation around the bronchoscope. This may lead both to difficulty ventilating the patient (especially those requiring maximum ventilatory support) and to the development of auto-PEEP and hyperinflation. The same bronchoscope inserted into an 8.0-mm ETT allows for an airway equivalent in cross-sectional area to that of a 6.0-mm ETT, which may allow for better ventilatory support of the patient.[2] However, as we discuss in the next section, changing the ETT can be a

high-risk procedure. There are alternatives to changing the ETT if bronchoscopy is necessary. The procedure can be performed through a 7.0-mm ETT with careful monitoring of the patient's ventilatory status and adjustments of ventilatory settings or manual ventilation, as needed. The bronchoscope can be inserted through the glottis anterior to the ETT, although this may result in a massive air leak in patients with low compliance, potentially compromising ventilation. A pediatric bronchoscope can also be used and should be long enough for most purposes. At our institution, we attempt to intubate all adult patients in the ICU with at least a 7.5-mm ETT to provide adequate ventilatory support if bronchoscopy is performed.

Tube size is also an issue in weaning from mechanical ventilation because of the concern over increased work of breathing. Under laminar flow conditions, ETTs cause airflow resistance that is directly proportional to their length and inversely proportional to the fourth power of their internal radius. As the inner diameter of the tube decreases, breathing becomes more difficult. However, the issue is whether this is clinically important and worth exposing the patient to the risk of changing the ETT. The results of a number of studies examining the work of breathing show that the increased work of breathing experienced in going from a 8.0-mm ETT to a 7.0-mm ETT is not great and can be easily overcome, if need be, by the addition of a small amount of pressure support.[2,15-17] Weissman has recently shown that 7.0- and 8.0-mm ETTs cause minimal limitations to airflow with the small volumes and low flows observed during tidal breathing.[18] If a patient cannot tolerate the minimal added work required to breathe through the smaller, 7.0-mm ETT, the patient's ability to cope with the added stresses of clearing secretions and preventing atelectasis after extubation must be questioned.

Finally, dynamic hyperinflation and, thus, auto-PEEP can occur as a result of a small ETT in the patient with obstructive lung disease who requires a high level of ventilation. Auto-PEEP, or intrinsic PEEP, is the resulting positive recoil pressure present at end expiration when the lungs fail to return to their true relaxation volume or functional residual capacity.[19] In contrast, extrinsic PEEP is a pressure intentionally applied through the external ventilator circuit. Auto-PEEP can be minimized either by decreasing ventilation (often difficult in the critically ill patient) or by increasing expiratory time. This latter goal can be achieved either by changing the inspiratory-to-expiratory-time ratio, decreasing the respiratory rate, or increasing inspiratory flows, which also reduces inspiratory time.[20]

### Changing the Endotracheal Tube

We have addressed many of the reasons why an ETT may have to be replaced, and now we focus on the methods to achieve this goal safely. Before a tube is changed, those involved in the care of the patient should be aware of the major risks of the procedure, which include aspiration of gastric contents and inability to reintubate the trachea with resultant hypoxic brain injury or death. The presence of an individual skilled in airway management is essential as is all necessary equipment (such as manual resuscitator, supplemental oxygen mask, oral airways, suction source and catheters, and all necessary airway instruments) before any airway manipulation is undertaken. If possible, the ETT should be changed under direct laryngoscopic vision with the aid of topical anesthesia, glossopharyngeal and superior laryngeal nerve blocks, and minimal or no sedation.[21] Adequate visualization of the glottis should be achieved before the old ETT is removed. Before the ETT is changed, pharyngeal suctioning should be performed and a vagolytic drug (eg, glycopyrrolate, 0.2-0.4 mg I.V.) administered to minimize secretions and the chance of bronchospasm. Muscle relaxants and intravenous anesthetics can be used in special situations; again, it is advisable to remove the old ETT under direct vision with a good view of the glottis. Direct laryngoscopy may be more difficult in an anesthetized and relaxed patient compared to an awake patient because the larynx may then become more anterior relative to other structures.[22]

If direct laryngoscopy does not provide adequate visualization, an alternative is to use a stylet, which when placed into the ETT prior to extubation serves as an intratracheal guide for reintubation. An NG tube can be used, but its flexibility may hinder the passage of the new ETT into the trachea. The pliable NG tube may enter the periphery rather than the center of the glottis, causing the ETT to be caught on the epiglottis or, more commonly, on the posterior commissure of the glottic opening. Manipulation of the neck, ETT, and NG tube, or use of a smaller ETT may permit successful passage. However, as the NG tube warms to body temperature, its flexibility may increase, further impairing its use as a guide. Cooling the NG tube in ice water prior to use may be helpful.[23] Coveler[24] has reported using an 18-French Salem Sump tube with the proximal end cut off to allow direct connection to a jet ventilator. In this fashion, the patient can be ventilated while the tube is being changed. The Eschmann introducer is a more rigid device available in several sizes and may be a more reliable ETT changer than an NG tube (Eschmann Health Care, West Sussex, England). This introducer can also be used as a stylet to aid in blind oral intubation. It can be modified as described by Artru et al[25] to permit measurement of end-tidal $CO_2$. At least two other tube changers are available: the Sheridan TTX™ tracheal tube exchanger in small, medium, and large sizes—medium being for tube sizes 6.0- to 8.5-mm ID (Sheridan Catheter Corp Argyle, NY), and the Cook Airway Exchange Catheter (Cook Critical Care, Bloomington IN) (Fig. 2). The Cook catheter is longer, stiffer, and thicker than the Sheridan and has attachable connectors for conventional (15-mm) and jet (Luer-Lok) circuits. Again, these blind stylet techniques are not fully dependable, and it may prove impossible to pass the ETT into the trachea. Fur-

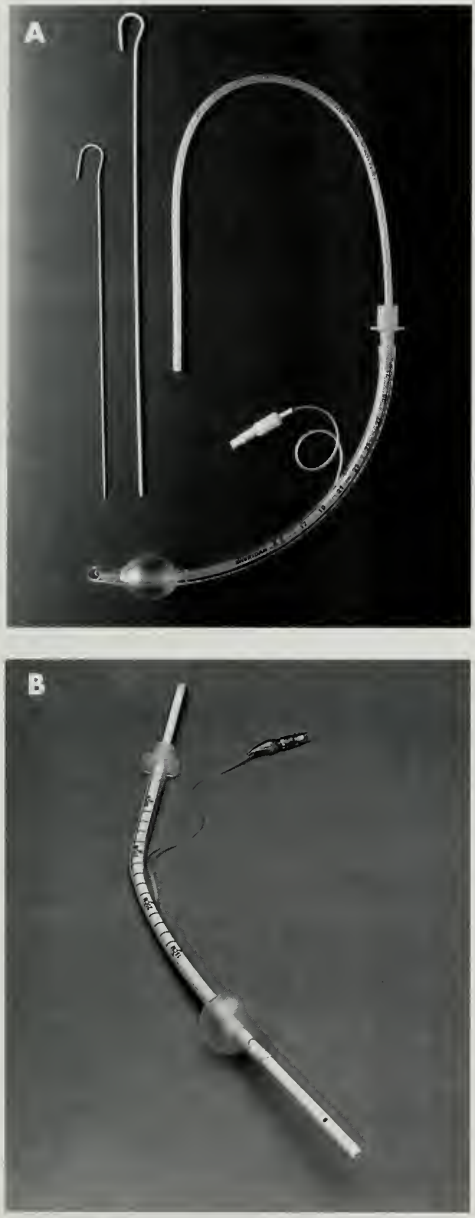


Fig. 2. Photographs of two endotracheal tube changers. A. The Sheridan TTX™ tracheal tube exchanger. B. The Cook Airway Exchange Catheter.

thermore, these stylets can cause damage to the tracheal mucosa and lung laceration.[26]

A 'jet-stylet' endotracheal catheter may provide additional safety during an ETT change. A jet stylet is a hollow, semi-rigid catheter that is inserted through an in situ ETT before extubation. After the ETT is removed over the stylet, the stylet can serve both to ventilate the patient (the jet function), and as a guide for reintubation (the stylet function). Gaughan et al[27] have shown that the jet stylet is capable of providing a minute ventilation consistent with total ventilatory support for most clinical situations. A simple and interesting method of changing a nasal tube to an oral tube has been reported. After removing the ETT adapter and deflating the cuff, the operator advances the ETT (and the pilot balloon) all the way through the nose until the proximal end of the tube can be grasped with a hemostat and withdrawn through the mouth. The adapter is then replaced, the cuff reinflated, and ventilation resumed.[28]

There are three methods by which the flexible fiberoptic bronchoscope (FOB) can be used to change the ETT. In the first method, a new ETT is placed over the FOB, and the scope is then passed well into the trachea alongside the ETT to be replaced, after slightly deflating the cuff. The old tube is removed, and the new one passed into position. If there is not sufficient room to pass the FOB into the trachea, the old tube can be removed under direct fiberoptic visualization, and subsequently the FOB can be placed into the trachea. This latter technique may not be as certain a method of securing the airway because the view may become obscured after tube removal. These two methods permit conversion of a nasally placed ETT to an oral one and vice versa. The third method allows only for changing tubes from nasal to nasal or oral to oral. In this method described by Hudes et al,[29] a new ETT is first placed over the scope, and the FOB is then placed through the existing ETT after removal of the 15-mm connector. The old tube is cut away with a No. 11 scalpel blade pointed away from the FOB as it is withdrawn. After the old tube is completely removed, the new one is inserted.[29] Benumof[30] described a combination of techniques in a patient with a difficult airway who required replacement of a nasal tube with an oral tube. In this case, the FOB was placed through a new ETT and then inserted into the patient's trachea via the oral route. A Sheridan tube exchanger was passed through the nasally placed ETT until it could be visualized just above the carina by the FOB. The nasally placed ETT was removed over the tube exchanger, and the orotracheal tube was passed over the FOB into the trachea. The FOB was withdrawn and after confirmation of correct tube placement with capnography, the tube exchanger was removed.[30] The value of this method is that, if the new ETT cannot be passed into the trachea, the patient can be jet ventilated either through the tube exchanger or through the suction port of the FOB, allowing further attempts at passage of the ETT or semi-elective performance of either cricothyrotomy or tracheostomy.

### Laryngotracheal Injury from Endotracheal Intubation

Many, perhaps most, standard ETTs used today are composed of polyvinyl chloride with high-volume, low-pressure cuffs. The advantage of this material over red rubber and silicone is its ability to soften at body temperature, which provides a stiffer tube for intubation that softens after placement, decreasing the pressure on laryngotracheal mucosa. However, despite these advantages, the possibility of pressure-point injuries at two levels exists: glottic injury due to pressure exerted by the wall of the tube, and tracheal injury due to pressure generated by the cuff or tip.

Laryngeal complications of endotracheal intubation result from pressure exerted by the tube on 3 structures: the cricoid cartilage and the 2 vocal processes of the arytenoids. Mucosal injury of the larynx may occur in the majority of intubated patients. In a dog model, Weymuller[31] has documented by fluorescein perfusion that ischemia is occurring within the first few hours of intubation due to the pressure exerted by the wall of the ETT, which may exceed the capillary perfusion pressure of the tracheal mucosa. Santos, Afriassiabi, and Weymuller[32] showed that after a mean of 10 days of intubation, nearly all (94%) patients evaluated exhibited vocal cord erythema and 67% had vocal cord ulceration. Injury at these sites is probably exacerbated by larger tube size and movement of the tube against the larynx during neck or tube displacement. Laryngeal mucosal injury can lead to serious complications of intubation: abscess in the retrocricoid region of the larynx and laryngeal stenosis. The presence of a cricoid abscess is suggested by the development of severe pain in the region of the larynx and may require antibiotic treatment and drainage.

The risk of laryngeal stenosis is high when the laryngeal injury is severe and deep ulceration has developed. Healing causes normal laryngeal structures to be replaced with scar tissue, leading to narrowing of the lumen and limitation of movement. The exact incidence of laryngeal stenosis is controversial. Whited[30] prospectively studied 200 patients who were intubated for prolonged periods and found a 14% incidence of clinically important laryngeal stenosis in those patients intubated for more than 10 days. In contrast, a review by Bishop et al[34] (including Weymuller) cite a 0-1% incidence of ETT-related laryngeal stenosis. Their review of all patients intubated for more than 10 days in 1981 from the Harborview Medical Center revealed that in 39 of 80 patients who survived hospitalization, none of the survivors had long-term laryngeal problems. The reason for the difference in these studies remains unclear.

Tracheal injuries have been markedly reduced by the use of ETTs with high-volume, low-pressure cuffs. The high-pressure cuffs in use until the 1970s created a seal by deforming the trachea around the inflated cuff. In contrast, modern cuffs achieve a seal by providing a larger surface area for contact with the mucosa, consequently lowering the incidence of ischemia and severe injury. However, despite these advances, it is essential to realize that a modern cuff can be inflated to pressures that induce injury. In order to avoid injury, it is recommended that cuff pressures be measured throughout any prolonged intubation and be kept < 25 cm $H_2O$.[35] In order for the cuff to protect against aspiration of gastric contents, a cuff pressure of 20-25 cm $H_2O$ is needed. It seems clear that it is not always a simple task to provide leak-free ventilation and protection from pulmonary aspiration, and to avoid tracheal injury due to excessive cuff pressure.

Accumulating data suggest that even cuff pressures below 25 cm $H_2O$ can lead to tracheal injury. Stauffer et al have shown that prolonged intubation with cuff pressures > 20 cm $H_2O$ is a significant correlate of tracheal injury. In an autopsy study, Donnelly[36] demonstrated a significant correlation between duration of intubation and laryngotracheal injury. Bunegin et al[37] have suggested that the application of the "maximum safe" pressure of 20-25 cm $H_2O$ may still have negative consequences because mucosal capillary perfusion pressure may not exceed 30 mm Hg (1 mm Hg = 1.36 cm $H_2O$). Their study revealed that application of a pressure of 20 mm Hg to the tracheal wall reduces tracheal blood flow by 75% at the cuff site. In a canine model, tracheal blood flow initially drops 57% within 1 hour of application of a cuff pressure at 15 mm Hg. Unlike the brain, the trachea is unable to autoregulate its blood flow during hypotension, further increasing the likelihood of injury when pressure is applied to the tracheal mucosa.[37] As a result, various cuff-inflation techniques have been advocated to minimize tracheal injury. Miller[38] described a pressure regulating device to prevent excessive cuff inflation pressure, and Jaeger et al[39] have used an automatic, intermittent cuff inflater. However, whether these methods can help reduce injury is debatable. In 1976, Powaser et al[40] showed that hourly cuff deflation was ineffective in reducing the extent of cuff-induced injury. Fortunately, although some degree of tracheal injury may be common at the cuff site, severe, function-limiting stenosis is uncommon. Diagnosis involves tracheal radiographs, fluoroscopy, and endoscopic examination, with tracheal dilatation on radiograph often being the first sign of injury.

The occurrence of a tracheoesophageal fistula is a rare complication of intubation. It usually develops slowly, and the first sign is often a cuff leak. Risk factors include high cuff and airway pressures, motion of the ETT, length of intubation, the presence of an NG tube, and the use of steroids. Treatment is difficult, and mortality is high; so, the emphasis should be on prevention.

### Extubation

Once the patient has been successfully weaned from ventilatory support, extubation can usually take place. All equipment and personnel needed for reintubation should be available. The mouth, nose, pharynx, ETT, and NG tube should

be adequately suctioned, and the patient should breathe 100% oxygen for 2 to 5 minutes. The suction catheter should not remain in the airway with suction applied as the ETT is removed because it may impair adequate oxygenation during extubation. Excessive suctioning should be avoided because it may stimulate coughing and bronchospasm, resulting in hypoxia, hypertension, and tachycardia. Furthermore, overzealous suctioning can cause uvular trauma.[41] The use of intravenous lidocaine prior to extubation is not recommended because it can cause transient respiratory depression in some patients; and, as Paulissian et al[42] have shown, it does not modify the modest hemodynamic responses of extubation. Just prior to extubation, the patient should be given a large, sustained breath, at which time the cuff is deflated and the ETT removed. This sequence dictates that the first postextubation event be a forceful cough, clearing the airway and vocal cords of secretions and reducing the incidence of postextubation laryngospasm and breath holding.[22] A "passive cough" method has been advocated as an alternate method of extubation. After adequate preoxygenation, the pressure relief valve of the ventilator is closed, and one or two breaths are administered. When the intrathoracic pressure has risen to 5-10 cm $H_2O$, the cuff is deflated and the trachea extubated.[43]

After extubation, sore throat and hoarseness are relatively common. The incidence of hoarseness in patients intubated only for the length of a surgical procedure is about 32%.[44] Vocal cord paralysis noted at the time of extubation is rare. It may result from surgery or trauma in the region of the vagus or recurrent laryngeal nerves or to injury induced by the ETT. Laryngeal dysfunction leading to inability to protect the airway from aspiration for a prolonged period after long-term intubation can be a serious problem. Consequently, patients initially should be fed with extreme caution, and some clinicians advocate withholding all oral intake for 24 hours following extubation. Laryngospasm is another potential postextubation problem. This can be treated by administering gentle positive pressure by mask but may require muscle relaxants and reintubation if severe.

A clinically important postextubation problem is glottic edema, which can cause complete airway obstruction and make reintubation necessary. The primary clinical symptom is stridor that usually occurs soon after extubation but may take several hours to become severe. Fortunately, severe stridor after extubation is uncommon, and reassurance, supplemental oxygen, and inhalation of cool, bland aerosols of water are usually all that is necessary. Inhaled racemic epinephrine is the treatment of choice if clinically important edema is present.[45] (Levo-epinephrine, the active component in racemic epinephrine, vasoconstricts the edematous tissue.) Racemic epinephrine has been shown to be effective in cases of viral croup, but its effectiveness is less well documented in cases of traumatic croup. Treatments may need to be repeated frequently to avoid reintubation and should be guided by heart rate and severity of stridor rather than by an exact dosing schedule. The potential for recrudescence of stridor 3 to 4 hours after treatment needs to be considered, and the administration of dexamethasone may prevent this rebound.[46]

Safe tracheal extubation of the patient with a difficult airway due to trauma, surgery, or burns is a challenge. The presence of a leak when the cuff is deflated is an encouraging but not entirely predictive sign of airway patency after extubation. Successful extubation following a positive cuff-leak test is likely. However, a failed cuff leak test does not preclude uneventful extubation.[47] If difficulty with the airway is anticipated, a jet-stylet catheter can be used for a trial of extubation to maintain access to the airway and to oxygenate and ventilate the patient if necessary. The FOB can also be used as an extubating stylet and has the additional advantages of providing suctioning and visualization of the airway. The laryngeal mask airway may have a place in managing ventilatory support of the extubated patient with a difficult airway.[48] Personnel capable of rapidly establishing a surgical airway should be available for any extubation of extreme risk.

## In Conclusion

Despite the wide use and apparent benefit of airway intubation for critically ill individuals, a myriad of potentially serious complications can occur. In this review, we have attempted to highlight some of these issues to help the clinician identify and manage common problems in patients requiring long-term intubation.

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# Sleep Apnea: Is Your Patient at Risk?

## A special article from the National Heart, Lung, and Blood Institute*

by Members of the
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**Diagnosis**
**Treatment Options**
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# Sleep Apnea: Is Your Patient at Risk?

## Definition and Prevalence

Sleep apnea is a serious, potentially life-threatening condition. It is a breathing disorder characterized by repeated collapse of the upper airway during sleep, with consequent cessation of breathing. Virtually all sleep apnea patients have a history of loud snoring. They may also unknowingly experience frequent arousals during the night, resulting in chronic daytime sleepiness or fatigue.

There are two discrete types of sleep apnea: central and obstructive. Central sleep apnea, characterized by a lack of airflow in the absence of ventilatory effort, is rare. Obstructive sleep apnea is much more common and is referred to as sleep apnea hereafter. It is characterized by closure of the upper airway, resulting in the cessation of airflow despite persistent ventilatory effort. Apnea is defined as cessation of airflow for more than 10 seconds. A related event, hypopnea, is characterized by a reduction in airflow associated with a decrease in oxygen saturation. The average number of apnea-hypopnea events per hour of sleep is called the apnea-hypopnea index (AHI). Adults may experience up to five events per hour without symptoms. In general, as AHI increases, so does the severity of symptoms. An AHI of five or greater in combination with self-reported hypersomnolence is indicative of the sleep apnea syndrome.[1]

Sleep apnea appears to be as common as some better known diseases. It is estimated that 4 percent of middle-aged men and 2 percent of middle-aged women meet minimal criteria for sleep apnea syndrome.[1] This compares to a 4.5 percent prevalence of asthma in middle-aged adults.[2] Sleep apnea is more prevalent among the obese, in males, and in older individuals.[3] There also seems to be a higher prevalence of sleep apnea in the hypertensive population.

## Consequences and Comorbidity

From a behavioral standpoint, sleep apnea patients usually experience but may or may not report tiredness, fatigue, sleepiness, memory and judgment problems, irritability, difficulty concentrating, and personality changes.[4] Patients with sleep apnea are more likely to fall asleep at inappropriate times and have a higher rate of automobile crashes[5] and work-related accidents.[4]

The cardiovascular system is also adversely affected by sleep apnea. Systemic hypertension has been reported in up to 50 percent of patients with sleep apnea.[6] Mean morning blood pressure has been shown to increase almost linearly with increasing apneic activity in both obese and nonobese individuals.[7] Cardiac arrhythmias during sleep have also been associated with sleep apnea. Usually bradyarrythmias are observed,[8] although ventricular tachycardia is noted occasionally in cases of severe hypoxemia.[9] It is possible that sleep apnea contributes to myocar-

dial ischemia, and even myocardial infarction, in patients with coronary artery disease.[10]

A small subset of patients with severe sleep apnea could be characterized as having the Pickwickian Syndrome (also known as obesity-hypoventilation syndrome), which consists of daytime hypercapnia and hypoxemia, pulmonary hypertension, polycythemia, and cor pulmonale.[11]

## IDENTIFICATION OF PATIENTS AT RISK FOR SLEEP APNEA

Patients at high risk for sleep apnea are those who exhibit loud, chronic snoring. If it can be confirmed that the patient does not snore, sleep apnea is unlikely. On the other hand, patients who are observed to have apneic events characterized by choking or gasping during sleep are definite candidates for further evaluation. Bed partners or family members will likely need to be interviewed in order to obtain accurate information about snoring and apneic events.

Obesity, particularly upper body obesity, is a risk factor for sleep apnea and has been shown to have a significant effect on its severity.[12] Most sleep apnea patients are obese, when obesity is defined as greater than 120 percent of ideal body weight.[13] Large neck girth in both male and female snorers is highly predictive of sleep apnea.[14] In general, men with a neck circumference of 17 inches or greater and women with a neck circumference of 16 inches or greater are at a higher risk for sleep apnea.[15]

Other signs and symptoms that can help identify patients at risk for sleep apnea are hypertension, excessive daytime sleepiness (especially dozing off while driving), automobile or work-related accidents, and otherwise unexplained pulmonary hypertension or cor pulmonale. See table 1.

**Table 1**

### PATIENTS AT RISK FOR SLEEP APNEA

**Symptoms**

- Chronic, loud snoring
- Gasping or choking episodes during sleep
- Excessive daytime sleepiness (especially drowsy driving)
- Automobile or work-related accidents due to fatigue
- Personality changes or cognitive difficulties related to fatigue

**Signs**

- Obesity, especially nuchal obesity (neck size $\geq$17 inches in males, $\geq$16 inches in females)
- Systemic hypertension
- Nasopharyngeal narrowing
- Pulmonary hypertension (rarely)
- Cor pulmonale (rarely)

If a patient complains of sleepiness but does not have other signs and symptoms suggestive of sleep apnea, a review of sleep habits may be helpful (e.g., how many hours of sleep the patient averages per night, recent changes in schedule, recent lifestyle changes). The patient may simply need to consider ways in which to increase the daily amount of sleep. If the patient is getting sufficient sleep, then other conditions such as narcolepsy or depression should be considered.

Sleep apnea is also seen in children. Tonsillar hypertrophy is the most common cause. Children with sleep apnea may exhibit different signs and symptoms than adults. During sleep, children exhibit snoring and labored breathing. Features compatible with sleep apnea include weight loss or failure to gain weight, poor school performance, secondary enuresis, and behavioral problems.[16-18]

## Diagnosis

If there is a high suspicion of sleep apnea after evaluating a patient, a sleep study is indicated to establish a diagnosis. Currently, polysomnography, which requires an overnight stay in a sleep laboratory, is the optimum test for diagnosing sleep apnea. It includes evaluation of sleep staging, airflow and ventilatory effort, arterial oxygen saturation, electrocardiogram, body position, and periodic limb movements. Polysomnography, however, may not be readily available. Other options to consider are evaluation using pulse oximetry and portable (home) monitoring of cardiopulmonary channels. Although oximetry is currently being used to diagnose sleep apnea, its sensitivity and specificity are controversial.[19] A variety of home monitors are currently available or being developed that can record both cardiopulmonary parameters (for example, airflow, ventilatory effort, heart rate, and oxygen saturation) and sleep parameters and may be useful in diagnosing sleep apnea.

It is imperative that a sleep study be interpreted by someone with expertise in sleep disorders since an accurate diagnosis is crucial to avoid undertreatment or overtreatment of patients.

The severity of symptoms will determine how quickly a sleep study should be obtained and therapy initiated. Patients who report falling asleep while driving or those with heart failure or angina are *high priority* for a sleep study and rapid intervention. Symptom severity along with availability of resources will determine the type of study and referral options.

## Treatment Options

The goals of treatment for sleep apnea patients include both physiologic and symptomatic components. Physiologic goals of treatment include eliminating sleep fragmentation, apneas and hypopneas, and oxygen desaturation. Symptomatic goals include eliminating snoring and sleepiness, improving quality of life, and reducing or eliminating comorbidities. Symptomatic improvement, particularly decreased snoring, does not necessarily correlate with physiologic improvement or decreased morbidity.

Therapy decisions must be individualized and are often accomplished in consultation with sleep apnea specialists. See table 2.

### Behavioral Approaches

Behavioral measures may be the only treatment needed for patients with mild sleep apnea. Behavioral interventions include losing weight, eliminating evening alcohol and sedatives, and proper positioning (avoiding the supine position in bed). Although weight loss (accomplished through a comprehensive program or surgery) may be difficult to achieve, it can be very effective and, in some cases, even curative.[20,21]

Table 2

**TREATMENT OF SLEEP APNEA**

- Modification of behavioral factors
  - Weight loss (including exercise regime)
  - Avoidance of alcohol and sedatives before sleep
  - Avoidance of supine sleep position
- Nasal CPAP
  - Noninvasive
  - Very effective
  - Patient adherence variable
- Oral/dental devices
  - May be useful in mild-to-moderate cases
  - Not uniformly effective
- Surgical procedures (UPPP, nasal surgery, tonsillectomy, LAUP, maxillofacial surgery, tracheostomy)
  - Invasive
  - Not uniformly effective
  - May carry risk
  - Repeat sleep study is necessary after each procedure

Patients with mild symptoms may experience improvement using behavioral techniques alone. Appropriate behavioral treatment should be implemented for all patients, even those requiring additional interventions.

Patients treated with behavioral techniques should be reevaluated periodically after initiation of treatment. For patients who have improved, continued support and positive reinforcement can sustain their adherence and success. In those patients who continue to experience symptoms, other therapies are warranted.

#### Nasal Continuous Positive Airway Pressure

Continuous positive airway pressure (CPAP) is the most effective noninvasive therapy for sleep apnea. To use CPAP, the patient must wear a sealed mask over the nose or, in some cases, over the nose and mouth during sleep.[22] The mask is connected to a blower forcing air through the nasal passages. CPAP acts as a pneumatic splint by increasing the pressure in the oropharyngeal airway, thereby maintaining airway patency throughout the ventilatory cycle.[23] This treatment is usually prescribed after polysomnography has first determined the therapeutic level of

CPAP pressure required to reduce or eliminate sleep apnea.[24] CPAP is effective in reversing daytime somnolence and eliminating cardiopulmonary sequelae.[25] CPAP, used properly, produces rhythmic breathing, resulting in the patient feeling dramatically better and being able to function more efficiently. Compared with no treatment or other treatment modalities, patients treated with CPAP have a lower mortality rate.[26]

Although very effective, CPAP may be difficult for some patients to use.[27] Adherence to CPAP treatment varies greatly but tends to be higher in patients with severe symptoms.[28] The most common reasons for discontinuing CPAP are intolerance of the mask, nasal-related complaints, and the inconvenience of being connected to a machine. Common side effects include nasal stuffiness, rhinitis, facial skin discomfort, and discomfort with the pressure. Humidifiers, nasal steroids or decongestants, intranasal anticholinergics, or different masks may relieve side effects. Variations in pressure application have been developed to offer patients options for improving comfort. Assisting patients to focus on symptom reversal and working with home care companies to ensure proper-fitting and effective equipment will enhance adherence.

Followup after the first month of CPAP treatment should include checking the status of equipment, assessing patient symptoms and adherence, and assessing the status of coexisting conditions such as hypertension. In patients who have achieved significant weight loss, the CPAP pressure may need to be adjusted. If the patient reports continued snoring, the pressure may need to be increased.

#### Oral/Dental Appliances

Oral or dental appliances may be an option for patients with mild-to-moderate sleep apnea. However, they are not effective in all patients. Appliances have also been used for patients who snore but do not have sleep apnea. There are various devices that displace the tongue forward or move the mandible to an anterior and forward position to improve patency of the airway.[29] Reported side effects of the devices include excessive salivation and temporomandibular joint discomfort. A dentist or orthodontist experienced in the use of these devices should fit the patient, and a sleep study should be done after the device is fitted to evaluate its effectiveness.

#### Surgical Procedures

Patients need to understand that no surgical procedure has universal success, and all are invasive and carry risk. Several procedures or a combination of procedures may need to be performed to help sleep apnea patients. It is important that sleep studies be repeated after each surgical procedure to confirm its effectiveness, once there is evidence of adequate healing. When weighing treatment options, it may be useful to let the patient know that CPAP is highly effective when used properly and is safe and reversible.[26,30]

***Uvulopalatopharyngoplasty (UPPP).*** During UPPP, an inpatient procedure, the uvula and portions of the soft palate are resected to widen the oropharyngeal airway. Although snoring is temporarily relieved in most cases, apnea may persist. The overall success rate of UPPP is reported to be about 40 percent (when success is defined as achieving an AHI of less than 20).[31] It is difficult to predict which patients will benefit from this procedure, and long-term side effects and benefits are unknown.

***Nasal Surgery.*** Nasal surgery may be used alone or in conjunction with other procedures. However, it is rarely curative alone.

*Tonsillectomy.* In children and adolescents adenotonsillectomy may be useful, even curative.[32] Tonsillectomy alone in adults is not usually helpful[33] but is often done in conjunction with UPPP.

*Laser-Assisted Uvulopalatoplasty (LAUP).* LAUP has received much attention recently as a treatment for snoring. However, its effectiveness in treating sleep apnea is unknown. LAUP differs from traditional UPPP in both surgical technique and setting (office-based). LAUP excises only part of the uvula and associated soft-palate tissues. The resultant shortening of the palate and reduction of the uvula may reduce, alter, or eliminate snoring. As with UPPP, relief of snoring may occur without improvement in apneic events. Therefore, patients who elect LAUP for snoring may risk delaying the diagnosis of sleep apnea because snoring, a primary symptom, is eliminated.[34]

*Maxillofacial Surgery (Genioglossal Advancement, Maxillary and Mandibular Advancement).* These are specialized procedures that are currently not widely available, although they appear to be effective in treating sleep apnea.[25] Genioglossal advancement enlarges the airway at the base of the tongue. This procedure may be combined with a UPPP. Maxillary and mandibular advancement enlarges the airway at the level of the soft palate as well as the tongue.

*Tracheostomy.* Tracheostomy is highly successful in eliminating sleep apnea but is very invasive, both physically and psychologically. This procedure is reserved for severe cases where other treatments have failed.

### Pharmacological Treatment

Currently, there are no safe and effective medications indicated in the routine treatment of sleep apnea.

### Oxygen

Administration of supplemental oxygen may improve nocturnal desaturation but is not a satisfactory treatment option by itself[35] because it does not reduce sleep disruption and subsequent daytime sleepiness.[36]

## Management Considerations

The efficacy of a chosen treatment modality should be periodically and objectively verified. Sleep apnea patients who undergo surgical interventions need to have sleep studies repeated postoperatively, after healing has occurred. Once effective treatment has been initiated, all patients should be periodically reevaluated for recurrence of symptoms such as snoring and excessive daytime sleepiness as well as cardiopulmonary complications. The primary care physician can play a key role in determining if patients are adhering to treatment and in monitoring comorbidities such as hypertension and coronary artery disease. For example, hypertension treatment may need to be adjusted once sleep apnea has improved. Patients who are adherent to treatment for sleep apnea need positive reinforcement, and those who are not adherent may require different treatment options. Patients who are on CPAP need to have their equipment evaluated periodically to ensure that the machine and mask are functioning properly.[23] If, however, symptoms of sleepiness persist despite apparently adequate treatment, the patient should be evaluated for other conditions.

## WHERE TO GET MORE INFORMATION

- **National Center on Sleep Disorders Research (NCSDR).** The NCSDR, located in the National Heart, Lung, and Blood Institute, supports research, scientist training, dissemination of health information, and other activities on sleep disorders and related concerns. The NCSDR also coordinates sleep research activities with other Federal agencies and with public and nonprofit organizations.

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- **National Heart, Lung, and Blood Institute Information Center.** The Information Center acquires, analyzes, promotes, maintains, and disseminates programmatic and educational information related to sleep disorders and sleep-disordered breathing. Write for a list of available publications or to order additional copies of this brochure.

  NHLBI Information Center
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# The American Association for Respiratory Care Clinical Practice Guidelines

- **Assessing Response to Bronchodilator Therapy at Point of Care**
- **Discharge Planning for the Respiratory Care Patient**
- **Long-Term Invasive Mechanical Ventilation in the Home**
- **Capnography/Capnometry during Mechanical Ventilation**
- **Selection of an Aerosol Delivery Device for Neonatal and Pediatric Patients**
- **Polysomnography**

*Respir Care 1995;40(12):1300-1343*

***Previously Published Guidelines:***

- Defibrillation during Resuscitation
- Management of Airway Emergencies
- Infant/Toddler Pulmonary Function Tests

*Respir Care 1995;40(7):744-768*

- Metabolic Measurement Using Indirect Calorimetry during Mechanical Ventilation
- Transcutaneous Blood Gas Monitoring for Neonatal and Pediatric Patients
- Capillary Blood Gas Sampling for Neonatal and Pediatric Patients
- Body Plethysmography

*Respir Care 1994;39(12):1170-1190*

- Ventilator Circuit Changes
- Delivery of Aerosols to the Upper Airway
- Neonatal Time-Triggered, Pressure-Limited, Time Cycled Mechanical Ventilation
- Application of Continuous Positive Airway Pressure to Neonates via Nasal Prongs or Nasopharyngeal Tube
- Surfactant Replacement Therapy
- Static Lung Volumes

*Respir Care 1994;39(8):797-836*

- Transport of the Mechanically Ventilated Patient
- Fiberoptic Bronchoscopy Assisting
- Resuscitation in Acute Care Hospitals
- Intermittent Positive Pressure Breathing
- Bland Aerosol Administration

*Respir Care 1993;38(11):1169-1200*

- Directed Cough
- Endotracheal Suctioning of Mechanically Ventilated Adults and Children with Artificial Airways
- In-Vitro pH and Blood Gas Analysis and Hemoximetry
- Single-Breath Carbon Monoxide Diffusing Capacity
- Use of Positive Airway Pressure Adjuncts to Bronchial Hygiene Therapy

*Respir Care 1993;38(5):495-521*

- Patient-Ventilator System Checks
- Humidification during Mechanical Ventilation
- Selection of Aerosol Delivery Device
- Nasotracheal Suctioning
- Bronchial Provocation
- Exercise Testing for Evaluation of Hypoxemia and/or Desaturation
- Arterial Blood Gas Sampling
- Oxygen Therapy in the Home or Extended Care Facility

*Respir Care 1992;37(8):855,856,882-922*

- Incentive Spirometry
- Pulse Oximetry
- Oxygen Therapy in the Acute Care Hospital
- Spirometry
- Postural Drainage Therapy

*Respir Care 1991;36(12):1398-1426*

# AARC Clinical Practice Guideline

## Assessing Response to Bronchodilator Therapy at Point of Care

**ARBD 1.0 PROCEDURE:**

Assessing response in adults and older children* to aerosolized bronchodilator therapy at the point of care. Although subjective responses and changes in mucociliary activity are important bronchodilator therapy effects, this guideline emphasizes the airway smooth muscle response that is primarily quantified through measurement of pulmonary function. It does not address initial diagnostic or ongoing (longitudinal) laboratory evaluation. A future Guideline will address assessment during mechanical ventilation.

**ARBD 2.0 DESCRIPTION:**

**2.1** Assessment of airflow (ie, forced expiratory maneuvers and other clinical indicators) is important to determine the presence or absence of an immediate response (ie, at time of expected onset of effect), proper dose, frequency of administration, and overall response to long-term therapy). It is essential that the clinician have complete knowledge of the main effects, mode of action, time course, side effects, and dosage constraints of any medications administered.

**2.2** This guideline addresses

- **2.2.1** subjective and objective measures of response;
- **2.2.2** frequency of monitoring;
- **2.2.3** expected or desirable outcomes.

**ARBD 3.0 SETTINGS:**

**3.1** Critical care
**3.2** Acute care
**3.3** Extended care or skilled care facility
**3.4** Outpatient clinic
**3.5** Home
**3.6** Pulmonary rehabilitation program

**ARBD 4.0 INDICATIONS:**

Assessment of airflow and other clinical indicators are indicated when the need exists

**4.1** to confirm the appropriateness of therapy;[2-4]
**4.2** to individualize the patient's medication dose per treatment and/or frequency of administration;[2-7]
**4.3** to help determine patient status during acute and long-term pharmacologic therapy;[2,8-10]
**4.4** to determine a need for change in therapy (dose, frequency, or type of medication).[2,11]

**ARBD 5.0 CONTRAINDICATIONS:**

When patients present in acute, severe distress, some assessment maneuvers may be contraindicated or should be postponed until therapy (eg, bronchodilator treatment) and supportive measures (eg, oxygen therapy) have been instituted.

**ARBD 6.0 HAZARDS/COMPLICATIONS:**

Hazards and complications include

**6.1** those associated with deep inhalation and forced exhalation

- **6.1.1** bronchoconstriction[12,13]
- **6.1.2** airway collapse[14]
- **6.1.3** paroxysmal coughing with or without syncope;[15,16]

**6.2** inherent hazards or complications of specific assessment procedures (ie, arterial puncture, esophageal balloons, forced exhalations).[16,17]

**ARBD 7.0 LIMITATIONS OF PROCEDURE OR DEVICE:**

**7.1** Conventional spirometry:

*For assessing responses in infants and toddlers, see AARC CPG Infant/Toddler PFT.[1]

**7.1.1** cost and accessibility

**7.1.2** the patient's inability to perform forced vital capacity.

**7.2** Peak-flow measurement

**7.2.1** Patient's inability to perform peak-flow maneuver or forced expiration.

**7.2.2** The accuracy and reproducibility of peak-flow meters may vary among models and among units of the same model.[2,18-22]

**7.2.2.1** For consistency and reproducibility of results the same device (unit) should be used for a given patient.[2,21]

**7.2.2.2** If peak-flow meter is changed, the patient's range should be re-established because of variability among units and models.

**7.2.2.3** Peak flow measurement primarily reflects changes in upper airway conductance and may be of limited use in evaluation of changes in peripheral airway conductance.[23,24]

**7.2.2.4** Evaluation of peak flow performance is subjective,[25] and, therefore, acceptability criteria are lacking. Because the maneuver is effort and volume dependent, the patient must be encouraged to perform as vigorously as clinically feasible (Three trials are desirable, with the best reported). Nose clips are not necessary, and the standing position is preferred.

**7.3** The results of subjective evaluation may be difficult to interpret consistently. A validated dyspnea rating scale may be useful.[26-30]

**7.3.1** Breath sound interpretation[31-34]

**7.3.2** Symptoms (eg, dyspnea)[27-29]

**7.4** The presence of an artificial airway increases resistance and, thus, increases work of breathing in the spontaneously breathing patient and may limit inspiratory and expiratory flows.[35,36]

**7.5** Techniques for monitoring response to bronchodilator in intubated, mechanically ventilated patients are different (eg, the flow-volume curve generated through an intubated airway may be difficult to interpret).[37-40] Accuracy and reproducibility of results may be affected by the mental and physical condition of the patient.[41] The measurement technology and, therefore, the results may vary from ventilator to ventilator.[40] Bronchodilator administration and assessment of response in the MV patient will be further addressed in a separate guideline.

## ARBD 8.0 ASSESSMENT OF NEED

**8.1** Response to therapy should be evaluated in all patients receiving bronchodilator therapy. (However, patient's in severe distress may need immediate treatment that precludes establishing a quantitative baseline).

**8.2** Assessment of response must be made with due regard for the patient's history, clinical presentation, and results of physical exam.

## ARBD 9.0 ASSESSMENT OF OUTCOME:

Assessment of outcome answers the question How did assessment of the effect of bronchodilator therapy impact on patient management?

**9.1** Action based on results of assessment

**9.1.1** Increase or decrease in dose and/or frequency

**9.1.2** Change medications

**9.1.3** Add medications

**9.1.4** Continue regimen

**9.1.5** Discontinue therapy

**9.2** To guide patient management, baseline condition and changes from baseline must be determined

**9.2.1** Prior to therapy:

**9.2.1.1** establish respiratory and cardiovascular baseline values;

**9.2.1.2** establish presence of clinical indicators and need for therapy;

**9.2.1.3** identify presence of contraindications.

**9.2.2** During therapy, identify:

**9.2.2.1** adverse responses to medication;

**9.2.2.2** any clinical change from baseline.

**9.2.3** Following therapy, identify:

**9.2.3.1** adverse responses;

**9.2.3.2** therapeutic responses (time course for peak varies with different medications);

**9.2.3.3** lack of therapeutic response.

**9.2.4** For trend analysis, identify:

**9.2.4.1** change in patient baseline;

**9.2.4.2** need to modify dose;

**9.2.4.3** need to change therapy;

**9.2.4.4** need to discontinue therapy;

**9.2.4.5** direction of change in bronchial responsiveness.

**9.3** Documentation:

**9.3.1** Patient response to medication

**9.3.1.1** Medication type, dose, and time received

**9.3.1.2** Responses measured: vital signs, breath sounds, lung function (eg, PEFR, $FEV_1$, $FEV_1$/.FVC), dyspnea score[26-29]

**9.3.1.3** Relate observations to time of medication administration and expected time of onset and peak response.

**9.3.2** Patient's progress

**9.3.3** Ability to self-assess and to recognize the need for more aggressive therapy and when and how to communicate with health professional.

**9.3.4** Record of symptoms and concurrent PEFR measurements should be kept for or by the patient at home.[2,42,43]

**ARBD 10.0 RESOURCES:**

**10.1** Equipment and other aids

**10.1.1** Instruments to measure expiratory flows: the choice of devices is based on cost, availability, and portability. When a portable laboratory spirometer that meets ATS standards[16,44] is available it should be used because results yield more information than is available from peak-flow measurement alone.

**10.1.1.1** Conventional spirometry with forced expiratory maneuvers is the standard for ***diagnostic*** measurement of bronchodilator response.[2,16,44]

**10.1.1.2** Peak flow measurement can be used for pre- and post-treatment measurement and for daily and trend monitoring.[2,8,45,46]

**10.1.2** Stethoscope

**10.1.3** Pulse oximeter

**10.1.4** Structured interview form for complete history; validated dyspnea indices.[2]

**10.1.5** Materials for patient and family education and diary[2,42,43]

**10.2** Resources—Personnel:

**10.2.1** Level II personnel—licensed or credentialed respiratory care practitioners (eg, RRT,[47] RPFT,[48] CPFT,[49] CRTT[50]) or persons with equivalent knowledge, training, and ability, who have documented that knowledge and demonstrated the necessary skills:

**10.2.1.1** to perform initial assessments and care for the unstable patient;

**10.2.1.2** to assess patient condition and response to therapy;

**10.2.1.3** to identify the indications for and effects of specific medication and equipment;

**10.2.1.4** to instruct patients in proper breathing patterns and coughing techniques;

**10.2.1.5** to modify therapy and appropriately care for the patient in response to adverse reactions;

**10.2.1.6** to modify dose, frequency, or delivery method or to change medication according to the patient's response, within the constraints of the protocol or the physician's direction;

**10.2.1.7** to use proper technique for administration of aerosols;

**10.2.1.8** to perform, interpret, and document conventional spirometry, peak expiratory flowrate, and ventilatory mechanics and to perform and document auscultation, inspection and assessment of vital signs, and

**10.2.1.9** to teach proper use of symptom diary and peak-flow meter;

**10.2.1.10** to develop, teach, and assess self-care plan for patient and family care giver;

**10.2.1.11** to properly use equipment, administer treatment, and make assessment in compliance with Universal Precautions and other infection-control procedures.[51,52]

**10.2.2** Level I personnel—licensed or credentialed respiratory care practitioners (eg, RRT,[47] RPFT,[48] CPFT,[49] CRTT[50]) or persons with equivalent knowledge, training, and ability, who have documented that knowledge and demonstrated the necessary skills:

**10.2.2.1** to observe, measure, monitor, and document response variables established with the patient's care plan (eg, use of diary and peak flow meter);

**10.2.2.2** to use proper technique for administration of medication;

**10.2.2.3** to properly use and clean equipment;

**10.2.2.4** to instruct patients in proper breathing patterns and coughing techniques;

**10.2.2.5** to modify therapy and patient care (within the constraints of the protocol or physician's directions) in response to changes in monitored variables, severity of symptoms, or adverse reactions and to communicate any modifications to Level-II provider or physician;

**10.2.2.6** to properly use equipment, administer treatment, and make assessment in compliance with Universal Precautions and other infection-control procedures.[51,52]

**10.2.3** Patient or family/caregiver providing maintenance therapy must know and demonstrate ability:

**10.2.3.1** to monitor or measure response to bronchodilator in accordance with the patient's care plan (use of symptom diary and peak-flow meter);[2,42,43]

**10.2.3.2** to use proper technique for administration of medication and correct use of devices (eg, MDI, spacer, peak-flow meter, small volume nebulizer);[2,7,43]

**10.2.3.3** to properly use and clean equipment;

**10.2.3.4** to modify doses and frequency as prescribed and instructed in response to adverse reactions or increase in severity of symptoms and to appropriately communicate with physician regarding severity of symptoms.

**ARBD 11.0 MONITORING:**

Monitoring seeks to establish baseline function and reveal the presence or absence of a desirable response to bronchodilator or other airway medication and to identify changes in airway reactivity in response to allergens, exercise, infection, or other causes. Desirable responses are:

**11.1** From observation of the patient

**11.1.1** General appearance is improved.

**11.1.2** Use of accessory muscles is decreased.

**11.1.3** Sputum expectoration is increased.

**11.2** From auscultation

Breath sounds may be improved, with a decrease in wheezing[2-5] or adventitious breath sounds ***and*** the volume of air moved ***is*** increased. (Decreased wheezing, eg, the 'silent' chest coupled with decreased volume of air moved can be an indication of a worsening condition rather than improvement.)

**11.3** Vital signs are more nearly normal.[53-55]

**11.4** Patient reports improvement[18,29,30] (eg, less dyspneic[56,57])

**11.5** From pulmonary function measurement: It is important to note that although correlation is generally high between values obtained by conventional spirometry and measurement of PEF, agreement may be poor for individual patients.[24,34,58]

**11.5.1** $FEV_1$, FVC,[27,58-61] and/or $FEF_{25-75\%}$[27,58,60] are improved.

**Note:** The ATS standards for a positive bronchodilator response in adults is "12% increase, calculated from the prebronchodilator response values, ***and*** a 200-mL increase in either FVC or $FEV_1$."[62] Dynamic compression of the airways during forced maneuvers may mask bronchodilator response in some patients, and for these patients the additional measurement of airway resistance and calculation of specific conductance may provide more diagnostic evidence.

**11.5.2** PEF[2,7,58,60,63] is increased.

**Note:** National Asthma Education and Prevention (NAEPP) Guidelines[2] provide detailed directions for use of the PEF in the asthmatic population.

**11.6** $S_{aO_2}$ (or $S_{pO_2}$),[2] and/or arterial blood gas values are improved (Effects of underlying chronic respiratory, metabolic, or other condition should be considered.)

**11.7** Exercise performance is improved as reflected by a more normal PEF during exercise or immediately following[63] or an increase in distance achieved during the 6-minute walking test[59]

**11.8** Ventilator variables are improved.[38-40,64]

**11.8.1** Lower PIP (during volume ventilation)

**11.8.2** Lower plateau pressure, increased static lung compliance.

**11.8.3** Decreased inspiratory and expiratory resistance

**11.8.4** Increased expiratory flow, improved flow-volume loop
**11.8.5** Decreased auto-PEEP

## ARBD 12.0 FREQUENCY

**12.1** Acute unstable patient:
**12.1.1** Whenever possible, perform a full assessment and obtain a pretreatment baseline.
**12.1.2** Perform arterial blood gas analysis on admission if patient is in severe distress.[2]
**12.1.3** Assess and document all appropriate variables before and after each treatment, (breath sounds, vital signs, side effects during therapy, PEF or $FEV_1$.[2]
**12.1.4** The frequency with which physical exam, PEF, and/or $FEV_1$ are repeated should be based on the acuteness and severity of the patient's condition.
**12.1.5** $S_{pO_2}$ should be monitored continuously, if possible.[2]
**12.1.6** Assessment should continue at each level of medication dose to optimal response for patient[5] (eg, asthmatic patient achieves 70-90% of predicted or "personal best" or is symptom free[2])
**12.2** Stable patient:[43,65]
**12.2.1** In the hospital setting, the PEF should be measured initially before and after each bronchodilator administration—to establish baseline function and to determine relative changes in function. Thereafter, twice daily determinations may be adequate.
**12.2.2** In the home, use the PEF 3-4 times a day (on rising, noon, 4-7 PM, and at bedtime)[2,66] to establish baseline function and to determine relative changes in function.
**12.2.2.1** For the stable COPD patient at home, twice a day measurements may be adequate.
**12.2.2.2** Asthmatic patients in the home will need to adjust the frequency of peak flow measurement according to their level of severity, with the development of symptoms, or with any deviation from baseline. Twice daily measurements (about 7 AM and 7 PM) are recommended for routine monitoring—(variability between these two measurements is a measure of severity.[2])
**12.2.3** The pre- and postbronchodilator PEFRs, medication dosage, date and time, and the dyspnea score should be documented.
**12.2.4** The patient should be periodically re-evaluated for response to therapy.

## ARBD 13.0 INFECTION CONTROL:

**13.1** Universal Precautions[47] and precautions related to the spread of tuberculosis as published by the Centers for Disease Control[48] should be followed.
**13.2** All equipment and supplies should be appropriately disposed of or subjected to high-level disinfection between patients.[67]

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# AARC Clinical Practice Guideline

## Discharge Planning for the Respiratory Care Patient

**DPRP 1.0 PROCEDURE:**

Development and implementation of a comprehensive plan for the safe discharge of the respiratory care patient from a health care facility and for continuing safe and effective care at an alternate site.

**DPRP 2.0 DESCRIPTION:**

The discharge plan is the mechanism that guides a multidisciplinary effort to achieve the successful transfer of the respiratory care patient from the health care facility to an alternate site of care. Implementation of the discharge plan is used to assure the safety and efficacy of the continuing care of the respiratory care patient.[1-10]

The discharge plan includes: (1) evaluation of the patient for the appropriateness of the discharge; (2) determination of the optimal site of care and of patient-care resources; and (3) determination that financial resources are adequate.

**DPRP 3.0 SETTING:**

The discharge plan can be developed at any site at which the respiratory care patient resides.

**DPRP 4.0 INDICATIONS:**

Discharge planning is indicated for all respiratory care patients who are being considered for discharge or transfer to alternate sites including the home. The alternate site may provide a higher or lesser level of care (depending on the patient's condition). The discharge plan should always be developed and implemented as early as possible prior to transfer.[11-13]

**DPRP 5.0 CONTRAINDICATIONS:**

There are no contraindications to the development of a discharge plan.

**DPRP 6.0 HAZARDS/COMPLICATIONS:**

Undesirable and/or unexpected outcomes may occur if the patient is discharged prior to the full implementation of the discharge plan. An undesirable and unexpected patient outcome may be a hazard or complication of the discharge plan; however, not all undesirable outcomes can be attributed to the discharge planning process but may be a result of the natural course of the disease or other factors beyond the control of the discharge planning process.

**DPRP 7.0 METHOD:**

Discharge planning and implementation should begin as early as possible. The complexity of the plan is determined by the patient's medical condition, needs, and goals. Members of the discharge planning team and their responsibilities should be identified and a coordinator specified. The steps in the planning process are:

**7.1** Patient evaluation:[2,8,11,14-16]

**7.1.1** The patient's medical condition

**7.1.2** The respiratory and ventilatory support required.[1,11,17]

**7.1.2.1** Mechanical ventilation

**7.1.2.1.1** Type, method of application, and duration

**7.1.2.1.1.1** Positive-pressure, negative-pressure, or other (eg, pneumatic belt, rocking bed, diaphragm pacer)

**7.1.2.1.1.2** Invasive (via tracheostomy) or noninvasive (all methods that do not include tracheostomy)

**7.1.2.1.1.3** Continuous—requiring ≥ 20 hours of ventilator assistance per day[18] or noncontinuous, which may be nocturnal only (requiring assistance only during hours of sleep) or other—requiring > 8 but < 20 hours of ventilator assistance per day.

**7.1.2.2** Other respiratory care and equipment:

**7.1.2.2.1** Oxygen therapy

**7.1.2.2.2** Aerosol therapy

**7.1.2.2.3** Airway clearance therapy

**7.1.2.2.4** Monitoring and diagnostic procedures

**7.1.2.2.5** Treatment for sleep-disordered breathing

**7.1.3** The patient's physical and functional ability, including acute and chronic neuromuscular conditions, other conditions, and activities of daily living.[1,12,14]

**7.1.4** The patient and family's psychosocial condition

**7.1.5** The patient and family's desires for medical and ventilator care.[1,12,19-22]

**7.1.6** The goals of care[1,5,11,14,23] from the perspective of the patient and family, the patient's physician, the health-care professionals who have and will be involved in the patient's care, and the bedside caregivers. These may include:

**7.1.6.1** treatment of acute medical conditions;

**7.1.6.2** weaning;

**7.1.6.3** rehabilitation;

**7.1.6.4** assurance of optimal quality of life.

**7.2** Site evaluation for continuing care

The primary factors to be considered in site determination are the goals and needs of the respiratory care patient. These goals and needs should be met in an optimal and cost-effective manner using the resources available at the alternate site.[1,3,5,8,11,22,24-30]

Possible sites for the respiratory care patient include acute, intermediate, and long-term care facilities, such as long-term acute, subacute, rehabilitation, skilled nursing facilities, and home. The respiratory care patient may transition among the sites according to changing medical condition.

The site must be evaluated for available resources:

**7.2.1** Personnel

**7.2.1.1** The staff of the selected health-care facility

**7.2.1.1.1** must clearly demonstrate and have documented (by the time of discharge) the competencies required for the patient's ventilatory and respiratory needs;

**7.2.1.1.2** must be able to provide other health-care services as may be indicated (eg, occupational and physical therapy).

**7.2.1.1.3** must be adequate for 24-hour coverage;

**7.2.1.2** For discharge to the home:

**7.2.1.2.1** The ability of the caregivers to learn and perform the required care must be evaluated.

**7.2.1.2.2** The caregivers must clearly demonstrate and have documented (by the time of discharge) the competencies required for caring for the specific patient.

**7.2.1.2.3** Availability of caregivers (lay and professional) for each 24-hour period must be assured.

**7.2.2** The chosen site must be capable of operating, maintaining, and supporting the equipment required by the patient's medical condition. This should include both respiratory and ancillary equipment and supplies as needed, such as the ventilator, suction, oxygen, intravenous therapy, nutritional therapy, and adaptive equipment.[1,14]

**7.2.3** Physical environment—The physical environment must be evaluated for safety and suitability. It should be[1,2,8,14,20,31,32] free of fire, health, and safety hazards; provide adequate heating, cooling, and ventilation; provide adequate electrical service; provide for patient access and mobility with adequate patient space (room to house medical and adaptive equipment) and storage facilities.

**7.3** Financial resources—Financial resources must be identified at the beginning of the discharge process. Lack of funding or inadequate funding impacts the entire discharge plan and can determine the care site.[1,2,5,6,8,11,16,19,20-22,25,27,28,33] It is essential to determine sources and adequacy of funds for alternate-site care, medical equipment and supplies, the required medical personnel, any modifications neces-

sary to environment, and ongoing medical care.

**7.4** Development of the plan of care—A multidisciplinary plan of care is developed based upon the evaluation of the patient's needs and goals. The plan should be consistent with recommended practices and guidelines for the patient's condition.[1,6,8,10,11,14,19,20,34,35] Key elements should include delineation of

- **7.4.1** plan for integration into the community;
- **7.4.2** plan for patient self-care as appropriate;
- **7.4.3** roles and responsibilities of team members for daily care management;
- **7.4.4** documented mechanism for securing and training additional caregivers;
- **7.4.5** alternative emergency and contingency plans;
- **7.4.6** plan for use, maintenance, and troubleshooting of equipment;
- **7.4.7** plan for monitoring and appropriately responding to changes in the patient's medical condition;
- **7.4.8** medication administration;
- **7.4.9** method for ongoing assessment of outcomes;
- **7.4.10** time frame for implementation;
- **7.4.11** method to assess growth and development of pediatric patients;
- **7.4.12** follow-up (eg, medical, respiratory care);
- **7.4.13** mechanism for communication among all members of healthcare team.

**7.5** Education and training with clear demonstration and documentation of competencies must occur prior to discharge. Education and training must address key elements of the plan of care.[1,2,6-9,17,22,27,28,30,33,36-38]

**7.6** Limitations of method:

Barriers to full implementation and discharge may occur due to[1,25,30,34,39]

- **7.6.1** patient's medical condition;
- **7.6.2** lack of availability of appropriate site;
- **7.6.3** lack of financial and patient care resources;
- **7.6.4** patient/family desires and cooperation;
- **7.6.5** failure to identify all pertinent problems or needs (including problems stemming from language or other barriers to communication).

**DPRP 8.0 ASSESSMENT OF NEED:**

All patients with a primary respiratory diagnosis should be assessed for the need for a discharge plan.

**DPRP 9.0 ASSESSMENT OF OUTCOME:**

The desired outcome of the discharge plan is determined by[19,40]

- **9.1** no re-admission to an alternate care site due to discharge plan failure;
- **9.2** satisfactory performance of all treatments and modalities by caregivers as instructed;
- **9.3** caregivers' ability to assess the patient, troubleshoot, and solve problems as they arise;
- **9.4** the treatment's meeting the patient's needs and goals;
- **9.5** the equipment's meeting the patient's needs;
- **9.6** the site's providing the necessary services;
- **9.7** the patient and family's satisfaction.

**DPRP 10.0 RESOURCES:**

The discharge planning process requires[1,3,5-8,16,22,31]

- **10.1** a written discharge plan that clearly delineates
  - **10.1.1** the educational materials, training aids and assessment tools;
  - **10.1.2** the amount of time anticipated to complete the process and discharge the patient;
  - **10.1.3** team member access to patient and family for information gathering and training;
  - **10.1.4** the source and limits of funds to implement the plan.
- **10.2** physical and financial support adequate to implement the discharge plan.
- **10.3** personnel.[1,3,5-8,16,22,31] One member of the team with particular expertise in respiratory care[1,5,16,22] should be designated to coordinate the efforts of all team members.
  - **10.3.1** patient;
  - **10.3.2** family and/or caregiver (lay or professional);
  - **10.3.3** physician;
  - **10.3.4** nurse;

**10.3.5** respiratory care practitioner;
**10.3.6** medical equipment provider;
**10.3.7** social worker;
**10.3.8** physical, occupational, and speech therapist, as indicated by patient condition;
**10.3.9** case manager;
**10.3.10** nutritionist;
**10.3.11** representative of the alternate site.

**DPRP 11.0 MONITORING:**

The discharge plan coordinator and the physician should monitor the progress of the discharge plan.[22] Each team member should participate in regularly scheduled team conferences to assess the progress of the discharge plan. Modifications may be made according to the individual patient's goals and needs.

**DPRP 12.0 FREQUENCY:**

The discharge planning process should be developed, reviewed, modified, and implemented whenever the patient is considered for transfer to an alternate site.

**DPRP 13.0 INFECTION CONTROL:**

The presence of transmissible infection and the presence of compromised immunity in the patient should be taken into consideration when discharge planning is undertaken. Appropriate steps to protect patient, caregiver, and family should be incorporated into the plan of care,[41,42] including provision for age-and condition-specific immunizations.[43]

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## Long-Term Invasive Mechanical Ventilation in the Home

**HIMV 1.0 PROCEDURE:**

The application of invasive mechanical ventilation and care of the patient-ventilator system in the home, as ordered by a physician.

**HIMV 2.0 DESCRIPTION/DEFINITION:**

Mechanical ventilation may be defined as a life support system designed to replace or support normal ventilatory lung function.[1] Ventilator dependence is caused by an imbalance between ventilatory capacity and demand.[2] "A ventilator-assisted individual (VAI) may require mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability" or to maintain life.[3] The patient eligible for invasive long term mechanical ventilation in the home (HIMV) requires a tracheostomy tube[4-6] for ventilatory support but no longer requires intensive medical and monitoring services.[7-9] This guideline refers to patients ventilated by positive pressure via a tracheostomy tube in the home.

The goals of HIMV are

**2.1** to sustain and extend life;[8,10-19]

**2.2** to enhance the quality of life;[10-15,17-29]

**2.3** to reduce morbidity;[8,10,11,13,16,20,30]

**2.4** to improve or sustain physical and psychological function of all VAIs[7,8,10,13,15,16,18,20,31,32] and to enhance growth and development in pediatric VAIs;[5,7,8,12,17-19,23,28,33-36]

**2.5** to provide cost-effective care.[7,8,10,11,13-19,22,23,27,28,32,36-45]

**HIMV 3.0 SETTING:**

The setting is the home, which for the purposes of this guideline may be the patient's home,[4,5,10,18,19,22,27,32,34,38,40,41,46-53] a foster home,[10,17] or a group-living environment.[10,51]

**HIMV 4.0 INDICATIONS:**

**4.1** Patients requiring invasive long-term ventilatory support have demonstrated:

**4.1.1** an inability to be completely weaned from invasive ventilatory support *or*

**4.1.2** a progression of disease etiology that requires increasing ventilatory support.

**4.2**.Conditions that met these criteria may include but are not limited to ventilatory muscle disorders,[4,5,10,11,14,16-19,21,26,27,33,35,38,42,43,46,52,54-62] alveolar hypoventilation syndrome,[4,5,10,17,18,19,23,33,34,42,43,46,47,59,60] primary respiratory disorders,[4,10,17,18,19,23,42,46,59,60] obstructive diseases,[5,10,57,58] restrictive diseases,[5,10,16,43,46,56] and cardiac disorders including congenital anomalies.[17,23,19,42,46,59]

**HIMV 5.0 CONTRAINDICATIONS**

Contraindications to HIMV include:

**5.1** The presence of a physiologically unstable medical condition requiring higher level of care or resources than available in the home.[4-7,10,14,16,17,19,20,21,23,26,29,33,52,59] Examples of indicators of a medical condition too unstable for the home and long term care setting are:

**5.1.1** $F_{IO_2}$ requirement > 0.40[4,5,10,16,35]

**5.1.2** PEEP > 10 cm $H_2O$[4,5,10,12,16,35]

**5.1.3** Need for continuous invasive monitoring in adult patients[4,6,16]

**5.1.4** Lack of mature tracheostomy

**5.2** Patient's choice not to receive home mechanical ventilation[5,10,16,19,23,26,39,42,52,56,58,63,64]

**5.3** Lack of an appropriate discharge plan[4,5,8,11,13,18,33,34,38,39,46,48,51,65]

**5.4** Unsafe physical environment as determined by the patient's discharge planning team.[10,13,66]

**5.4.1** Presence of fire, health or safety hazards including unsanitary conditions.[39,51]

**5.4.2** Inadequate basic utilities (such as heat, air conditioning, electricity).[4,5,10,19,22,33,38,39,52,67]

**5.5** Inadequate resources for care in the home:

**5.5.1** Financial[9,10,13,14,16,18,19,23,25,26,33,35,38-40,44,52,55,56,59,68,69]

**5.5.2** Personnel

**5.5.2.1** Inadequate medical follow-up[13,14,16,18,29,33,36,38,39,50,61]

**5.5.2.2** Inability of VAI to care for self, if no caregiver is available[5,16]

**5.5.2.3** Inadequate respite care for caregivers[17,19,26]

**5.5.2.4** Inadequate numbers of competent caregivers[5,13,21,23,25,26,30,38,39,52,68]

## HIMV 6.0 HAZARDS AND COMPLICATIONS

**6.1** Deterioration or acute change in clinical status of VAI. Although ventilator-associated complications in the home are poorly documented, experience in other sites can be extrapolated. The following may cause death or require rehospitalization for acute treatment.

**6.1.1** Medical: Hypocapnia, respiratory alkalosis,[70] hypercapnia, respiratory acidosis, [70] hypoxemia, barotrauma,[5,64,70] seizures, hemodynamic instability,[21] airway complications (stomal or tracheal infection, mucus plugging, tracheal erosion or stenosis),[5] respiratory infection (tracheobronchitis, pneumonia),[57,70,71] bronchospasm,[5] exacerbation of underlying disease, or natural course of the disease

**6.1.2** Equipment-related: Failure of the ventilator, malfunction of equipment,[10] inadequate warming and humidification of the inspired gases, inadvertent changes in ventilator settings, accidental disconnection from ventilator,[27] accidental decannulation

**6.1.3** Psychosocial: Depression,[5,10,43] anxiety,[4,10,43] loss of resources—caregiver or financial,[10,19,25,40,43] detrimental change in family structure or coping capacity[5,10,19,25,34,38,54,55,56,71,72]

## HIMV 7.0 LIMITATIONS

In the home care setting, making and implementing changes in the plan of care may take longer than in a health care facility.

## HIMV 8.0 ASSESSMENT OF NEED

**8.1** Determination that indications are present and contraindications are absent.

**8.2** Determination that the goals listed in 2.1 can be met in the home.

**8.3** Determination that no continued need exists for higher level of services.

**8.4** Determination that frequent changes in the plan of care will not be needed.

## HIMV 9.0 ASSESSMENT OF OUTCOME

At least the following aspects of patient management and condition should be evaluated periodically as long as the patient receives HIMV

**9.1** Implementation and adherence to the plan of care

**9.2** Quality of life

**9.3** Patient satisfaction

**9.4** Resource utilization

**9.5** Growth and development in the pediatric patient

**9.6** Unanticipated morbidity, including need for higher level site of care.

**9.7** Unanticipated mortality

## HIMV 10.0 RESOURCES

**10.1** Equipment

**10.1.1** Ventilator(s)—Choice should be based on patient's clinical need,[5,10,14,22,23,35,38,67,73] Patient's medical needs may dictate that more than one ventilator be provided.

**10.1.1.1** Ventilators chosen for home care must be dependable and easy for the intended caregivers to operate; small size and lightweight are desirable

**10.1.1.2** Mobility is frequently an essential element of the plan of care of the patient. The mechanical ventilator system chosen for such a patient should allow mobility.

**10.1.2** With portable, volume-cycled ventilators, use of the SIMV mode increases work of breathing, and the addition of an

external continuous-flow system reduces portability.[1,10,74-76]

**10.1.3** Complex and nonportable components are not recommended for HIMV but may be used to meet the needs of certain pediatric patients.[10,13,22,35,75]

**10.1.3.1** Ventilators powered by external compressed gas sources are less desirable.[10,22]

**10.1.3.2** A second ventilator should be provided for

**10.1.3.2.1** patients who cannot maintain spontaneous ventilation for 4 or more consecutive hours;[4,10,13,67]

**10.1.3.2.2** patients who live in an area where a replacement ventilator cannot be provided within 2 hours;[4,13,39,67]

**10.1.3.2.3** patients who require mechanical ventilation during mobility as prescribed in their plan of care.

**10.1.4** An adequate power source must be available to operate the ventilator consistent with patient needs.[4,5,10,13,14,39,67] This may be supplied by one or more of the following methods:

**10.1.4.1** Alternating current (AC) is the primary power source for most long-term care ventilators. Emergency AC power should be available in the long-term care facility.

**10.1.4.2** Direct current (DC) by external battery may be used to allow mobility and as an emergency power source. The internal battery of the ventilator should be used only for short-term, emergency use. It should not be used as a primary source of power.

**10.1.5** Alarms

**10.1.5.1** A patient-disconnect (eg, low-pressure[10] or low-exhaled-volume) and a high-pressure alarm are essential.

**10.1.5.2** If patient disconnection is likely to produce a serious adverse effect, a remote alarm and a secondary alarm may be indicated. A secondary alarm may be based on chest-wall impedance and cardiac activity, exhaled volume, end-tidal $CO_2$, or pulse oximetry with alarm capabilities.[42]

**10.1.6** Humidification system(s) are essential for invasive mechanical ventilation. The type of system used is determined by the patient's medical needs[77] and the patient's need for mobility.[10,13,35] It may be appropriate for the patient to use more than one type of system, based on those needs.[1,15,78,79-81]

**10.1.6.1** Heated humidifier (temperature probes should be provided).

**10.1.6.2** Heat and moisture exchanger can be used during transport and to enhance mobility.[1,77,81]

**10.1.7** Ventilator circuit and accessories as medically indicated.

**10.1.8** Self-inflating resuscitation bag with tracheostomy attachments and mask of appropriate size[5,10,21-23,39,67]

**10.1.9** Replacement tracheostomy tube of appropriate size plus a tube one size smaller should be available at all times.

**10.1.10** Suction equipment[5,10,13,21-23,39,62,67] including a battery-powered aspirator for patients who leave the home or when indicated as an alternate source in the event of a power failure

**10.1.11** Supplemental oxygen as medically indicated[10,13,39,67]

**10.1.12** Patients must have an adequate means of communicating their needs and desires and to summon help in the case of emergency.[10]

**10.2** Personnel:

**10.2.1** Lay caregivers (eg, family members, personal care attendants, and non-credentialed health care personnel such as nurse's aides) can be taught skills and techniques of care for a specific VAI. Appropriately trained lay caregivers must demonstrate competency in

**10.2.1.1** proper set up, use, troubleshooting, and maintenance of the equipment and supplies;[10,23,32,33,39,40,50,65]

**10.2.1.2** patient assessment and ongoing response to invasive mechanical ventilation;[10,23,32,33,35,40,65]

**10.2.1.3** responding to the hazards of invasive mechanical ventilation;[22,23,26,33]

**10.2.1.4** responding to emergencies;[10,23,32,39,40] in the case of

**10.2.1.4.1** power failure;

**10.2.1.4.2** acute life threatening events such as accidental decannulation[22] or other need for tracheostomy tube replacement,[10] other unexpected events, or medical deterioration of the patient

**10.2.1.4.3** failure of equipment or supplies;

**10.2.1.5** complying with appropriate infection control procedures;[10,39,65]

**10.2.1.6** providing appropriate return demonstrations in the use and application of any additional techniques required for the ongoing care of the VAI, such as suctioning and use of ancillary equipment;[10,39,40,50,65]

**10.2.2** Level-II practitioners are healthcare professionals capable not only of providing direct patient care but also possessing demonstrated competencies to monitor and assess both the patient and equipment. Level-II practitioners are capable of training and evaluating lay caregivers. Level-II practitioners should be credentialed health care professionals (eg, RRT, CRTT, RN) with documented knowledge and demonstrated competencies to:

**10.2.2.1** provide knowledge and understanding of the patient's disease, goals and limitations of invasive mechanical ventilation;[32,33,39]

**10.2.2.2** assess patient's response to invasive mechanical ventilation;

**10.2.2.3** make recommendations for changes in respiratory management of patient, including weaning as necessary;[10,33]

**10.2.2.4** train and monitor caregivers;[4,5,10,32,33,40,50]

**10.2.2.5** monitor patient's ongoing ventilatory status;

**10.2.2.6** communicate results of assessment to the health care team.[5,39]

**10.3** Finances: HIMV can only be instituted and maintained with adequate financial resources to provide the necessary equipment and personnel to manage the patient's care.[10,13,35,43]

## HIMV 11.0 MONITORING

The frequency of monitoring should be determined by the ongoing individualized care plan and be based upon the patient's current medical condition. The ventilator settings, proper function of equipment, and the patient's physical condition should be monitored and verified: (1) with each initiation of invasive ventilation to the patient, including altering the source of ventilation, as from one ventilator or resuscitation bag to another ventilator; (2) with each ventilator setting change; (3) on a regular basis as specified by individualized plan of care.[35]

All appropriately trained caregivers should follow the care plan and implement the monitoring that has been prescribed. These caregivers may operate, maintain and monitor all equipment and perform all aspects of care required by the VAI after having been trained and evaluated on their level of knowledge for that equipment and the VAI's clinical response to each of the interventions.

**11.1** Lay caregivers should monitor the following regularly:

**11.1.1** Patient's physical condition: respiratory rate, heart rate, color changes, chest excursion, diaphoresis, and lethargy, blood pressure, body temperature.

**11.1.2** Ventilator settings: The frequency at which alarms and settings are to be checked should be specified in the plan of care.

**11.1.2.1** Peak pressures

**11.1.2.2** Preset tidal volume

**11.1.2.3** Frequency of ventilator breaths

**11.1.2.4** Verification of oxygen concentration setting

**11.1.2.5** PEEP level (if applicable)

**11.1.2.6** Appropriate humidification of inspired gases

**11.1.2.7** Temperature of inspired gases (if applicable)

**11.1.2.8** Heat and moisture exchanger function

**11.1.3** Equipment function:[10,13]

**11.1.3.1** Appropriate configuration of ventilator circuit[82]

**11.1.3.2** Alarm function

**11.1.3.3** Cleanliness of filter(s)—according to manufacturer's recommendation

**11.1.3.4** Battery power level(s)—both internal and external

**11.1.3.5** Overall condition of all equipment

**11.1.3.6** Self-inflating manual resuscitator—cleanliness and function

**11.2** A Level-II practitioner should perform a thorough, comprehensive assessment of the patient and the patient-ventilator system on a regular basis as prescribed by the plan of care. In addition to the variables listed in 11.1.1-11.1.3. the Level-II practitioner should implement, monitor, and assess results of other interventions as indicated by the clinical situation and anticipated in the care plan.

**11.2.1** Pulse oximetry—should be used in patients requiring a change in prescribed oxygen levels or in patients with a suspected change in condition.[10,35]

**11.2.2** End-tidal $CO_2$—may be useful for establishing trends in $CO_2$ levels during weaning.[10,23,33,35,59,83,84]

**11.2.3** Specimen collection (and analysis as applicable) as prescribed by physician—including but not limited to sputum and blood work (eg, arterial blood gas analysis and complete blood counts).[5,10,32,37]

**11.2.4** Cardiorespiratory monitoring (electrocardiogram, heart-rate trending)[10]

**11.2.5** Pulmonary function testing

**11.2.6** Ventilator settings

**11.2.7** Exhaled tidal volume

**11.2.8** Analysis of fraction of inspired oxygen

**11.3** Level-II personnel are also responsible for maintaining interdisciplinary communication concerning the plan of care

**11.4** Level-II personnel should integrate respiratory plan of care into the patient's total care plan.[10] Plan of care should include

**11.4.1** all aspects of patient's respiratory care[66] and

**11.4.2** ongoing assessment and education of the caregivers involved.

## HIMV 12.0 FREQUENCY:

**12.1** The frequency of ventilation (and the patient's ventilator-free time) is dictated by the patient's physiologic needs and is determined in consultation with the patient's physician.

**12.2** The frequency of assessment of the VAI and the patient-ventilator system must be noted in the evolving total care plan as determined by the health care team, in conjunction with the VAI and their caregivers.

## HIMV 13.0 INFECTION CONTROL

**13.1** Both professional and lay caregivers should be aware of the potential for transmission of both chronic and acute infection from patient to caregiver and from caregiver to patient and should take the steps necessary to avoid that transmission. Aspects of avoidance include:

**13.1.1** careful handwashing and barrier protection when appropriate

**13.1.2** careful disposal of medical waste

**13.1.3** adequate environmental air exchange

**13.1.4** maximizing protection of patient, family, and caregivers (eg, influenza immunization) and minimizing exposure to persons with acute infections (eg, limiting visitors with upper respiratory infections).

**13.2** Evidence is lacking to support an optimal plan for changing and processing ventilator circuits and ancillary equipment in the home. However, studies from institutional settings[85,86] suggest that ventilator circuits need not be changed more often than once each week. Further, it appears that the less often a circuit is entered, the less likely contamination is to occur.

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# AARC Clinical Practice Guideline

## Capnography/Capnometry during Mechanical Ventilation

### $CO_2$ MV 1.0 PROCEDURE:

Capnography comprises the continuous analysis and recording of carbon dioxide concentrations [$CO_2$] in respiratory gases. Although the terms capnography and capnometry are sometimes considered synonymous, capnometry suggests measurement (ie, analysis alone) without a continuous written record or waveform.

### $CO_2$ MV 2.0 DESCRIPTION/DEFINITION:

For the purposes of this Guideline, capnography refers to the evaluation of the [$CO_2$] in the respiratory gases of mechanically ventilated patients. A capnographic device incorporates one of two types of analyzers: mainstream or sidestream.[1,2] Mainstream analyzers insert a sampling window into the ventilator circuit for measurement of $CO_2$, whereas a sidestream analyzer aspirates gas from the ventilator circuit, and the analysis occurs away from the ventilator circuit. Analyzers utilize infrared, mass or Raman spectra, or a photoacoustic spectra technology.[3,4]

### $CO_2$ MV 3.0 SETTING:

This procedure may be performed by trained health care personnel in any setting in which mechanically ventilated patients are found—for example, the hospital, the extended care facility, or during transport.

### $CO_2$ MV 4.0 INDICATIONS:

On the basis of available evidence, capnography should not be mandated for all patients receiving mechanical ventilatory support, but it may be indicated for

**4.1** evaluation of the exhaled [$CO_2$], especially end-tidal $CO_2$, which is the maximum partial pressure of $CO_2$ exhaled during a tidal breath (just prior to the beginning of inspiration) and is designated $P_{etCO_2}$;[5,6]

**4.2** monitoring severity of pulmonary disease[5] and evaluating response to therapy, especially therapy intended to improve the ratio of dead space to tidal volume ($V_D/V_T$)[7,8] and the matching of ventilation to perfusion (V/Q),[9] and, possibly, to therapy intended to increase coronary blood flow;[5,10,11]

**4.3** determining that tracheal rather than esophageal intubation has taken place (low or absent cardiac output may negate its use for this indication);[12-16]

**4.4** continued monitoring of the integrity of the ventilatory circuit, including the artificial airway;[12,15]

**4.5** evaluation of the efficiency of mechanical ventilatory support by determination of the difference between the arterial partial pressure for $CO_2$ ($P_{aCO_2}$) and the $P_{etCO_2}$;[17,18]

**4.6** reflecting $CO_2$ elimination;[19]

**4.7** monitoring adequacy of pulmonary and coronary blood flow;[10,11,20-22]

**4.8** monitoring inspired $CO_2$ when $CO_2$ gas is being therapeutically administered;[23]

**4.9** graphic evaluation of the ventilator-patient interface. Evaluation of the capnogram may be useful in detecting rebreathing of $CO_2$, obstructive pulmonary disease, waning neuromuscular blockade ('curare cleft'), cardiogenic oscillations, esophageal intubation, cardiac arrest, and contamination of the monitor or sampling line with secretions or mucus.[24]

### $CO_2$ MV 5.0 CONTRAINDICATIONS:

There are no absolute contraindications to capnography in mechanically ventilated adults provided that the data obtained are evaluated with consideration given to the patient's clinical condition.

**$CO_2$ MV 6.0 HAZARDS/COMPLICATIONS:**

Capnography with a clinically approved device is a safe, noninvasive test, associated with few hazards. With mainstream analyzers, the use of too large a sampling window may introduce an excessive amount of dead space into the ventilator circuit.[2,25] Care must be taken to minimize the amount of additional weight placed on the artificial airway by the addition of the sampling window or, in the case of a sidestream analyzer, the sampling line.

**$CO_2$ MV 7.0 LIMITATIONS OF PROCEDURE OR DEVICE:**

Capnography, when performed using a device calibrated and operated as recommended by the manufacturer, has few limitations. It is important to note that although the capnograph provides valuable information about the efficiency of ventilation (as well as pulmonary and coronary perfusion), it is not a replacement or substitute for assessing the $P_{aCO_2}$.[17,24,26-28] The difference between $P_{etCO_2}$ and $P_{aCO_2}$ increases as dead-space volume increases. In fact, the difference between the $P_{aCO_2}$ and $P_{etCO_2}$ has been shown to vary within the same patient over time.[29-32]

Certain situations may affect the reliability of the capnogram. The extent to which the reliability is affected varies somewhat among types of devices (infrared,[33] photoacoustic, mass spectrometry, and Raman spectrometry). Limitations include

**7.1** The composition of the respiratory gas mixture may affect the capnogram (depending on the measurement technology incorporated).

**7.1.1** The infrared spectrum of $CO_2$ has some similarities to the spectra for both oxygen and nitrous oxide.[33] High concentrations of either or both oxygen or nitrous oxide may affect the capnogram, and, therefore, a correction factor should be incorporated into the calibration of any capnograph used in such a setting.[34]

**7.1.2** The reporting algorithm of some devices (primarily mass spectrometers) assumes that the only gases present in the sample are those that the device is capable of measuring.[35] When a gas that the mass spectrometer cannot detect (such as helium) is present, the reported values of $CO_2$ are incorrectly elevated in proportion to the concentration of helium present.

**7.2** The breathing frequency may affect the capnograph. High breathing frequencies may exceed the response capabilities of the capnograph.[36] In addition, the breathing frequency, above 10 breaths/min, has been shown to affect devices differently.[37]

**7.3** The presence of Freon (used as a propellant in metered dose inhalers) in the respiratory gas has been shown to artificially increase the $CO_2$ reading of mass spectrometers (ie, to show an apparent increase in $[CO_2]$). A similar effect has not yet been demonstrated with Raman or infrared spectrometers.[38]

**7.4** Contamination of the monitor or sampling system by secretions or condensate, a sample tube of excessive length, a sampling rate that is too high, or obstruction of the sampling chamber can lead to unreliable results.

**$CO_2$ MV 8.0 ASSESSMENT OF NEED:**

Capnography is considered a standard of care during anesthesia.[12] The Society of Critical Care Medicine has suggested that capnography be available in every ICU.[39] Assessment of the need to use capnography with a specific patient should be guided by the clinical situation. The patient's primary cause of respiratory failure and the acuteness of his or her condition should be considered. Patients with severe dynamic disease, such as ARDS, should be considered candidates for capnography.[5,6]

**$CO_2$ MV 9.0 ASSESSMENT OF OUTCOME:**

Results should reflect the patient's condition and should validate the basis for ordering the monitoring. Documentation of results (along with all ventilatory, and hemodynamic variables available), therapeutic interventions, and/or clinical decisions made based on the capnogram should be included in the patient's chart.

**$CO_2$ MV 10.0 RESOURCES:**

**10.1** Equipment: The capnograph and accessories (eg, airway adapter, sampling tube, depending on capnograph). The capnograph

should be calibrated as recommended by the manufacturer, with calibration quality gases in the clinical range of [$CO_2$].

**10.2** Personnel: Licensed or credentialed respiratory care practitioners or individuals with similar credentials (eg, MD, RN) who have the necessary training and demonstrated skills to correctly calibrate and evaluate the capnograph, assess the patient and the patient-ventilator system, and the ability to exercise appropriate clinical judgment.

## $CO_2$ MV 11.0 MONITORING:

During capnography the following should be considered and monitored

**11.1** ventilatory variables: tidal volume, respiratory rate, positive end-expiratory pressure, inspiratory-to-expiratory time ratio (I:E), peak airway pressure, and concentrations of respiratory gas mixture;[24,26]

**11.2** hemodynamic variables: systemic and pulmonary blood pressures, cardiac output, shunt, and ventilation-perfusion imbalances.[24,26]

## $CO_2$ MV 12.0 FREQUENCY:

Capnography (or, at least, capnometry) should be available during endotracheal intubation.[12,13,15,26] Capnography is not indicated for every mechanically ventilated patient; however, when it is used, the measurement period should be long enough to allow determination of the $P_{aCO_2}$-$P_{etCO_2}$ difference, note changes in $P_{aCO_2}$-$P_{etCO_2}$ difference as a result of therapy, and allow interpretation of observed trends.

## $CO_2$ MV 13.0 INFECTION CONTROL:

No specific precautions are necessary although Universal Precautions (as described by the Centers for Disease Control & Prevention)[40] and precautions designed to limit the spread of tuberculosis[41] should always be implemented during patient care.

**13.1** The sensor (the portion of the device contacting the patient's airway) should be subjected to high-level disinfection between patients, according to the manufacturer's recommendations.

**13.2** The monitor (the portion not contacting the patient or the patient's airway) should be cleaned as needed according to manufacturer's recommendations.

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# AARC Clinical Practice Guideline

## Selection of an Aerosol Delivery Device for Neonatal and Pediatric Patients

**NPAM 1.0 PROCEDURE:**

This guideline addresses the appropriate selection of a device for the administration of aerosolized medications by small volume nebulizer (SVN), large volume nebulizer (LVN), metered dose inhaler (MDI), and dry powder inhaler (DPI) to neonatal and pediatric patients. Recommendations are made for patients both with and without an artificial airway, those spontaneously breathing, and those requiring assisted positive-pressure breathing. Evidence suggests that in pediatric patients a properly used MDI is as effective for delivering medications as is an SVN.[1-5]

**NPAM 2.0 DESCRIPTION:**

Effective administration of medication as aerosol depends on the delivery system and its position in relation to the patient.[6,7] Aerosol particle deposition is influenced by particle size, ventilatory pattern, and airway architecture.[8] Effective medication response is also influenced by the dose of the medication used.[9-12] In the neonatal and pediatric population, the process for determining the doses of specific aerosolized medications is not completely understood.[13] Drug pharmacokinetics and pharmacodynamics are markedly altered in neonates and may require dose adjustments.[13-16] This guideline addresses characteristics of an aerosol delivery system.

This guideline provides recommendations to assist the clinician in selecting an aerosol delivery device based on the patient's ability. Identifying the ability of the patient (ie, coordination and generated flows, rather than specific age requirements) is essential to selecting the appropriate aerosol delivery device in any population.

The three principal elements of an aerosol delivery system are the generator, the power source, and the interface.[6,7] Generators include small volume nebulizers (SVN), large volume nebulizers (LVN), metered dose inhalers (MDI), and dry powder inhalers (DPI).[7,17] The power source is the mechanism by which the generator operates or is actuated and includes compressed gas for SVN and LVN and self-contained propellants for MDI.[7,17] The interface is the conduit between the generator and the patient and includes spacer devices/accessory devices with mouthpieces or face masks.[7,17] Depending on the patient's age (ability) and coordination, various interfaces are used in conjunction with SVN and MDI in order to optimize drug delivery.[7,17]

A SVN is a jet nebulizer that is powered by a compressed gas source. The medication is displaced up a capillary tube from the nebulizer's reservoir and is dispersed continuously as aerosolized particles.[7] The aerosolized particles are spontaneously inhaled by the patient or delivered in conjunction with positive-pressure breaths.[6,7] For patients > 3 years who are spontaneously breathing without an artificial airway and are able to cooperate, a mouthpiece with an extension reservoir should be used.[6,7] For patients unable to negotiate a mouthpiece (usually < 3 years), a face mask should be used.[18,19]

A MDI is a pressurized canister that contains a medication and propellant. Actuation of the MDI results in the ejection of one dose of medication as aerosolized particles, which can be spontaneously inhaled by the patient or delivered in conjunction with positive-pressure breaths.[7] A spacer device/accessory device should be used with an MDI. A spacer device enhances delivery by decreasing the velocity of the particles and reducing the number

of large particles.[20,21] A spacer device with a one-way valve, ie, holding chamber, eliminates the need for the patient to coordinate actuation and inhalation and optimizes drug delivery.[20,21] A spacer device without valves requires coordination between inhalation and actuation. The MDI with spacer device and face mask is appropriate for patients (usually < 3 years) unable to use a mouthpiece.[18,22-27]

A DPI is a breath-actuated device that uses a gelatin capsule containing a single dose of medication and a carrier substance to aid in the dispersion of the drug.[7] The capsule is inserted into the device and punctured.[28] The patient's inspiratory flow disperses the dry particles and draws them into the lower airways.[28] In spontaneously breathing patients, this device is appropriate in patients who are able to achieve an inspiratory flow ≥ 50 L/min. This usually corresponds to children > 6 years of age.[13,29]

A LVN can be used to deliver a dose of medication continuously over a period of time.[30,31] A LVN is powered by a compressed gas source, and a face mask is typically used as the interface.[30] There has been only limited investigation of its use in the neonatal and pediatric population.

**NPAM 3.0 SETTING:**

Aerosolized medications can be administered in a number of settings including hospitals, clinics, extended care facilities, the home, and during transportation.

**NPAM 4.0 INDICATIONS:**

An aerosol delivery system is indicated when a medication approved for inhalation is prescribed.

**NPAM 5.0 CONTRAINDICATIONS:**

**5.1** Contraindications associated with specific medications may exist. Pharmaceutical information should be consulted for relative contraindications.

**5.2** An MDI or DPI should not be used

**5.2.1** for patients with known allergies to medication preservatives;

**5.2.2** for patients unable to perform the respiratory maneuver required to disperse/deliver the drug.

- **NPAM 6.0 HAZARDS/COMPLICATIONS:**

**6.1** Aerosol delivery

**6.1.1** Malfunction of device and/or improper technique may result in underdosing. Overuse may result in overdosing.[32,33]

**6.1.2** Specific pharmacologic agents can produce adverse side effects.[34]

**6.1.3** The prescription of aerosol delivery devices for use in the home can lead to misuse if the user has not been properly trained.[33-35]

**6.2** SVN

**6.2.1** Continuous nebulizer flow increases tidal volume and associated pressure during volume-targeted ventilation.[36-38]

**6.2.2** Continuous flow creates a bias flow in the ventilator circuit and may interfere with patient-triggered modes of ventilation.[36-39]

**6.2.3** Continuous flow of aerosol may damage the expiratory flow transducers found in some ventilators.[37]

**6.2.4** The continuous flow of gas from a flowmeter or compressor to an inline nebulizer used with a continuous-flow ventilator may result in an excess of flow and may cause an increase in airway pressure and/or expiratory retard or PEEP.

**6.2.5** The continuous flow of gas from a flowmeter or compressor to an in-line nebulizer used with a ventilator may result in variable $F_{IO_2}$s.

**6.2.6** Aerosol particles may deposit and crystallize on expiratory mechanisms and may create inadvertent expiratory resistance or PEEP.[36,37]

**6.2.7** Medication reservoirs may become contaminated and can be a source of infection.[40]

**6.2.8** Diluents that are not isotonic may increase airway reactivity.[34]

**6.3** MDI

**6.3.1** The volume of gas discharged with actuation of the canister/inhaler may add a clinically important volume to tidal volume particularly in neonates.[37]

**6.3.2** Additional dead-space volume can

occur when a spacer device is placed at the end of an artificial airway.

**6.3.3** Volume of gas discharged from MDI may affect $F_{IO_2}$.

**6.3.4** Inappropriate patient use may result in underdosing or overdosing.

**6.3.5** Reaction to propellants and other additives including coughing and wheezing may occur.[34,41,42]

**6.3.6** Chlorofluorocarbons may contribute to ozone depletion.[43-45]

**6.3.7** Oropharyngeal impaction from corticosteroid supplied in MDI form may result in local side effects.[7,46]

**6.4** DPI

**6.4.1** Airway irritation from dry powder may occur.[7,28]

**6.4.2** Reaction to lactose or glucose carriers may occur.[7,28]

**6.5** LVN

**6.5.1** Side effects may occur at any time during continuous nebulization, and frequent assessment is required.[30,31]

**6.5.2** Medication reservoirs may become contaminated and can be a source of infection.[40]

**NPAM 7.0 LIMITATIONS OF PROCEDURE OR DEVICE:**

**7.1** SVN

**7.1.1** Deposition of medication into the lungs is reduced to as little as 2-10% of the dose,[6,8,14,47-52] and may vary from brand to brand and unit to unit of the same brand.

**7.1.1.1** Patients with smaller tidal volumes, particularly neonates[14,53-55] or dyspneic patients with shallow breathing may inhale less of the aerosolized agent and receive less of the dose when nebulization is continuous.[14,47,52]

**7.1.1.2** Patients with airways of smaller diameter may receive a smaller fraction of the total particles produced.[14,53,55-57]

**7.1.1.3** High inspiratory flows, as those associated with crying, may reduce deposition.

**7.1.1.4** Approximately one half the initial solution volume is deposited on the internal walls and reservoir of the SVN.[6,8,47,58-60]

**7.1.1.5** Concentration of the solution increases during nebulization resulting in retention of much of the dose in the SVN.[6,8,47,58,59] The effects of changing osmolality on bronchoreactivity are not clear.

**7.1.1.6** Aerosol is lost during the expiratory phase of breathing.[6]

**7.1.1.7** Treatment length may result in premature termination prior to complete nebulization of medication.[36]

**7.1.1.8** Fill volume in the SVN affects the output.[58]

**7.1.2** Use is labor intensive and costly.[61-64]

**7.1.3** Duration of treatment is variable and may be prolonged.[6,7,61,62] (Increasing diluent volume lengthens treatment time but may improve drug delivery.[8,58])

**7.1.4** The need for a power source makes the SVN less portable, particularly in the home setting.[6,7]

**7.1.5** SVNs require preparation and cleaning.[7]

**7.1.6** The brand of SVN used (ie, those that operate effectively only in the upright position).

**7.2** SVN in conjunction with positive-pressure breathing.

**7.2.1** Impaction of aerosol particles on artificial airways greatly reduces deposition.[37,65-71] The presence of artificial airways of smaller diameter results in a greater reduction in particle deposition and delivered dose.[6,7,67,71,72] The smaller the artificial airway, the greater the reduction in particle deposition.

**7.2.2** Limited research on use of aerosols in neonatal and pediatric patients has been published.[37,54,73]

**7.2.3** Aerosol delivery may be less effective in conjunction with manual ventilation than with mechanical ventilation.[13,72]

**7.2.4** Mechanical ventilator modes, flows, and flow patterns may affect particle deposition.[25,65,66,74]

**7.2.5** The presence of an in-line humidifier may reduce aerosol delivery by 50%.[37]

**7.2.6** Use of SVN with continuous-flow

ventilators may result in the loss of a large percentage of the aerosolized particles through the exhalation valve.[37]

**7.2.7** Positioning of the SVN too close to the artificial airway results in less airway deposition.[37,65,66,69,75]

**7.3** SVN with face mask

**7.3.1** Cold, wet mist may be irritating to children and may limit the time that the treatment is tolerated.[13]

**7.3.2** Nasal breathing results in a reduction in particle deposition.[57,76,77]

**7.3.3** Particle deposition is reduced because of upper airway impaction.[57,76,77]

**7. 4** MDI

**7.4.1** Use of an MDI without a spacer device with one-way valve (ie, holding chamber), requires the patient to coordinate the actuation of the canister with inhalation, which may be particularly difficult for small children (eg, < 7 years).[13,78]

**7.4.2** Use of an MDI without a spacer device results in greater oropharyngeal impaction and a reduction in airway deposition.[6,7,78,79]

**7.4.3** Use of an MDI without a spacer device may result in a cold sensation when the propellant reaches the back of the throat (ie, cold-Freon effect) that may interfere with proper delivery technique.[7,17,80]

**7.4.4** Inadequate or inaccurate instruction and technique may result in misuse and reduced aerosol deposition.[13,81-83]

**7.4.5** Propellants may cause bronchospasm in some patients with reactive airway diseases.[41]

**7.4.6** Average deposition in the lungs is 10% to 25% of the total dose.[49,84-86]

**7.4.7** Particle size varies with operating pressure which is directly related to canister temperature.

**7.5** MDI with spacer device

**7.5.1** Addition of the spacer/accessory device increases cost over cost of the MDI alone.[6,7]

**7.5.2** The spacer/accessory device is relatively cumbersome and less convenient than the MDI alone.[6,7]

**7.5.3** All spacer/accessory devices may not fit all MDIs.

**7.5.4** All spacer devices/accessory devices do not eliminate coordination problems.

**7.5.4.1** A spacing/accessory device with a one-way valve (ie, holding chamber) eliminates coordination problem.

**7.5.4.2** Open tube spacer/accessory devices (non-valved) require coordination.

**7.6** MDI with spacer device-face mask—The inspiratory flow and the number of inhalations required by neonates and small children (< 3 years) to effectively use these devices is not completely understood.[13,52,54,87]

**7.7** MDI with spacer device designed for mechanical ventilation

**7.7.1** Research is limited in this population.[13,21]

**7.7.2** The smaller the diameter of the artificial airway, the greater the reduction in particle deposition and delivered dose.[13,37,88]

**7.7.3** Particle deposition may be as low a 2-10% of the total drug delivered.[13,3769,89-91]

**7.7.4** Use of an elbow-type spacer results in less airway deposition than a chamber-type spacer.[36,87,89,92]

**7.7.5** The chamber type spacer if left inline with a ventilator circuit potentially increases the compressible volume of the ventilator circuit.

**7.7.6** The gas discharged from the MDI may affect $F_{IO_2}$.

**7.8** DPI

**7.8.1** Reduced inspiratory flow (< 50 L/min) can lead to reduced deposition.[14,29,92,93] This may be more likely in children < 6 years[13,29] and in an acute exacerbation when peak flows are significantly reduced.

**7.8.2** Some drug preparations are water soluble and, thus, humidity may affect DPI performance.[6,7]

**7.8.3** Oropharyngeal impaction of much of the dose occurs and results in a reduction in lower airway deposition.[14,28]

**7.8.4** The patient must be able to load each dose, for most medications.[47]

**7.8.5** Average deposition in the lungs is 10-25% of the total dose.[7,13,92,94]

**7.9** LVN with mask

**7.9.1** The use of LVN for continuous nebulization in the pediatric population has not been widely investigated.[30,95]

**7.9.2** Cold, wet mist may be irritating to children and may limit the time that the treatment is tolerated.[13]

**7.9.3** Nasal breathing results in a reduction in lower airway deposition.[57,76,77]

**7.9.4** Bronchial deposition is reduced because of upper airway impaction.[57,76,77]

**7.9.5** Limited to use in a critical care setting. Not appropriate for home use.

**7.10** Drug pharmacokinetics and pharmacodynamics are markedly altered in neonates and may require dose adjustments.[13-16]

**NPAM 8.0 ASSESSMENT OF NEED:**

**8.1** SVN: General Indications

**8.1.1** The need to deliver aerosolized medications that are approved in solution form to the lower airway of spontaneously breathing patients with or without an instrumented airway.[6,7,13]

**8.1.2** The need to provide supplemental gas flow in conjunction with aerosol treatment.[7]

**8.1.3** The need to modify drug concentration.[7]

**8.1.4** The need to deliver a particular aerosolized medication that is only available in solution form.

**8.1.5** The need to deliver aerosolized medications to patients in acute distress or with reduced inspiratory flow.

**8.1.6** The need to deliver aerosolized medications to patients who are unable to coordinate or perform the necessary inspiratory maneuvers required with an MDI or DPI.

**8.2** SVN with mouthpiece and extension reservoir—The need to deliver aerosolized medications approved in solution form to the lower airways of spontaneously breathing patients without an instrumented airway who are able to utilize a mouthpiece (patients > 3 years).[6,7]

**8.3** SVN with face mask

**8.3.1** The need to deliver aerosolized medications that are approved in solution form to the lower airways of spontaneously breathing patients without an instrumented airway who are unable to negotiate a mouthpiece (usually < 3 years).[18,19]

**8.3.2** The need to deliver aerosolized medications to the upper airway.

**8.4** SVN with T-connector (15-mm and 22-mm openings)

**8.4.1** The need to deliver aerosolized medications approved in solution form inline with a mechanical ventilator circuit or manual resuscitation bag.[74,96]

**8.4.2** The need to deliver aerosolized medications approved in solution form to patients with instrumented airways who are spontaneously breathing.

**8.5** MDI: General indications

**8.5.1** The need to deliver aerosolized medications that are approved in MDI form.[18]

**8.5.2** The need to deliver a particular medication that is only available in MDI form.

**8.5.3** The need to reduce the length of time for the aerosol treatment.

**8.5.4** The need for maximum portability.[55]

**8.6** MDI with spacer device with one-way valve—

**8.6.1** The spacer device with one-way valve and face mask is appropriate for small children (usually < 3 years) and others unable to use a mouthpiece.[18,22-27,97]

**8.6.2** The need to eliminate actuation and inspiratory maneuver coordination.[20,21]

**8.6.3** The need to reduce oropharyngeal impaction,[20,21]particularly with the delivery of corticosteroids by inhalation.[98,99]

**8.6.4** The valved-spacer device with mouthpiece is the method of choice if patient is able to use a mouthpiece.

**8.6.5** A specially designed spacer device is used for MDI-delivery during mechanical ventilation or with manual resuscitators.[73,100]

**8.7** MDI with a non-valved spacer device

**8.7.1** The need to use a MDI when a patient can coordinate inspiration and actuation.

**8.7.2** The need to reduce oropharyngeal impaction,[20,21] particularly with the delivery of corticosteroids by inhalation.[98,99]

**8.9** DPI

**8.9.1** The need to deliver aerosolized medications approved in DPI form.[38,101,102]

**8.9.2** The need to deliver a particular

medication that is only available in DPI form.[38,101,102]

**8.9.3** The need to eliminate chlorofluorocarbon propellants.

**8.10** LVN—The need to deliver continuously aerosolized medication, approved in solution form, to the lower airway of spontaneously breathing patients without an instrumented airway.[31]

## NPAM 9.0 ASSESSMENT OF OUTCOME:

**9.1** Desired medication effect is observed as indicated by an improvement in subjective (physical examination) and objective (pulmonary function measurements) assessments.[19,31,103-108]

**9.2** Health care providers demonstrate competency with proper technique and patient instruction of aerosol delivery systems.[33]

**9.3** Patients and patients' family members demonstrate proper technique and compliance with the application of aerosol delivery systems.[33]

## NPAM 10.0 RESOURCES

**10.1** Equipment

**10.1.1** SVN capable of producing a high drug output, short nebulization time, aerosol particles with a mass median aerodynamic diameter (MMAD) $\leq 5\ \mu$, and with a low residual volume.[8,55,58,60] Characteristics of nebulizers may vary among brands and among units of the same brand.

**10.1.1.1** Power source such as hospital compressed oxygen or air, portable oxygen or air cylinder, or domiciliary air compressor capable of producing a flow of at least 6-8 L/min.[6-8,58,108]

**10.1.1.2** A blender for use with a ventilator to maintain desired $F_{IO_2}$.

**10.1.2** Interface

**10.1.2.1** Face mask for small children unable to utilize a mouthpiece which may include an additional 6-inch section of aerosol tubing.[18,19]

**10.1.2.2** Mouthpiece with extension reservoir.[6]

**10.1.2.3** T-connector with 15- and 22-mm openings or tracheostomy collar adaptation for patients with artificial airway and/or receiving aerosolized medications in conjunction with a manual resuscitation bag.

**10.1.2.4** T-connector with inspiratory circuit reservoir for patients receiving aerosolized medications in conjunction with mechanical ventilation.[65]

**10.1.3** Medication and isotonic diluent.

**10.1.3.1** MDI, which includes the medication canister and actuator, with appropriate accessories for patient's ability and circumstances.

**10.1.3.1.1** Chamber-style spacer with mouthpiece or mask, depending on the patient's ability.[109]

**10.1.3.1.2** Chamber-style spacer with inspiratory circuit configuration for patients receiving aerosolized medications in conjunction with mechanical ventilation.[91]

**10.1.3.1.3** Chamber-style spacer configured for patients with artificial airways and/or receiving aerosolized medications in conjunction with a manual resuscitation bag, placed between airway and bag.

**10.3.1** DPI with accompanying medication capsule and dispenser.

**10.4.1** LVN capable of producing aerosol particles with a mass median aerodynamic diameter (MMAD) $\leq 5\ \mu$ with face mask.

**10.5** Personnel

**10.5.1** Health care providers responsible for delivery of aerosolized medications should have demonstrated and documented knowledge and skills related to

**10.5.1.1** aerosol delivery devices and their limitations;[110]

**10.5.1.2** assembly, care and use of aerosol delivery devices;[110]

**10.5.1.3** provision of comprehensive patient and lay caregiver instruction;[18,111,112]

**10.5.1.4** medications being delivered including contraindications, potential side effects and desired response;[110]

**10.5.1.5** recognition and response to adverse reactions during medication delivery and modification of treatment accordingly;[110]

**10.5.1.6** performance of the necessary subjective and objective assessments in order to determine medication efficacy and the patient's ability to properly utilize aerosol delivery devices.

**10.5.2** Patient and/or family member or lay caregiver should

**10.5.2.1** demonstrate proper use and understanding of aerosol delivery device and delivery technique;[32,108]

**10.5.2.2** demonstrate proper assembly, cleaning, care of aerosol delivery device, and medication preparation;[32,108]

**10.5.2.3** demonstrate an understanding of medication purpose, dosage, indications, and side effects, be able to alter medication as needed,[108] and know when to report to physician or surrogate.

## NPAM 11.0 MONITORING

**11.1** Observe delivery technique of spontaneously breathing patients who are able to self-administer aerosolized medications.

**11.1.1** A slow deep inhalation with an inspiratory pause/hold is performed during SVN treatments.[55] A flow of 6-8 L/min and fill volume of 4 mL (dependent upon the brand of SVN used) provide a maximum volume of delivered drug.[53] The sides of the SVN are periodically tapped in order to minimize the dead volume (ie, volume of solution not nebulized) and maximize the volume nebulized.[53]

**11.1.2** MDI actuation occurs at end-exhalation followed by a slow inspiration and breath hold for 10 seconds.[55,111,112]

**11.1.3** Patient is able to produce a rapid inhalation in order to fully activate and discharge DPI.[101]

**11.2** Observe patient and/or patient's family member following instruction and demonstration.[108]

**11.2.1** Proper understanding and return-demonstration of delivery device and accompanying equipment is observed.[47,108]

**11.2.2** Proper understanding and preparation of medication is observed.[47,108]

**11.3** Observe response to medication by performing subjective (eg, physical examination) and objective (eg, pulmonary function measurements) assessments and other diagnostic techniques that are appropriate for the specific medication being delivered.[19,31,103-107]

**11.3.1** Ensure that medication volume is nebulized over desired amount of time when using LVN.

**11.3.2** Continuous monitoring of ECG is recommended when delivering a bronchodilator by LVN.

**11.4** Monitor ventilator function for inadvertent increases in tidal volume or airway pressures, changes in $F_{IO_2}$, difficulty with patient triggering and patient-ventilator synchrony, or other system problems.[36]

**11.5** Documentation

**11.5.1** Successful training of patients and/or patient's family member are documented in the patient's medical record.[33,108]

**11.5.2** Treatments administered in a clinical setting are documented in the patient's medical record. Information on medication dose, frequency, response and adverse reactions are included.

## NPAM 12.0 FREQUENCY

Aerosol delivery devices are used according to the frequency of the prescribed medication.

## NPAM 13.0 INFECTION CONTROL

**13.1** Universal Precautions and measures to limit the transmission of tuberculosis must be adhered to at all times.[113,114]

**13.2** SVN are for single patient use.

**13.2.1** Between treatments on the same patient, disinfect, rinse with sterile water, and air-dry.[40] In the home environment, cleaning, rinsing with solution of vinegar and water, and air drying may be adequate, although clear evidence to support this procedure is lacking.

**13.2.2** Between patients, replace SVN with those that have undergone high level disinfection or sterilization.[40]

**13.3** MDI, DPI and accessories are for single patient use only. Clean or replace when they appear dirty.

**13.4** LVN are for single patient use. LVN

should be subjected to high-level disinfection or sterilization between patients.

**13.5** Aerosol solutions.

**13.5.1** Use only sterile fluids and dispense them aseptically.[40]

**13.5.2** Medications obtained from multi-dose vials are handled, dispensed and stored according to manufacturers' instructions.

**13.6** Patients with a natural airway should be instructed to rinse the mouth with water following each administration of inhaled steroids.

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# AARC-APT Clinical Practice Guideline

## Polysomnography

This Guideline was developed jointly by the AARC Cardiopulmonary Diagnostics CPG Focus Group and representatives of the Association of Polysomnography Technologists (APT). Both groups have approved its content.

**PSG 1.0 PROCEDURE:**

Polysomnography

**PSG 2.0 DESCRIPTION/DEFINITION:**

Polysomnography refers to the collective process of monitoring and recording physiologic data during sleep. The specific variables monitored during center-based polysomnographic evaluation of sleep-related respiratory disturbances are listed.[1,2] Home-based polysomnography[3] and unattended monitoring systems are not addressed in this guideline.

The variables monitored and recorded during polysomnography include but are not limited to:[4,5]

**2.1** global neural electroencephalographic activity (EEG) from electrodes placed on the patient's scalp;

**2.2** eye movements (electro-oculogram, or EOG) from electrodes placed near the outer canthus of each eye;

**2.3** submental electromyographic activity (EMG) from electrodes placed over the mentalis, submentalis muscle, and/or masseter regions;

**2.4** rhythm electrocardiogram (ECG) with two or three chest leads;

**2.5** respiratory effort, by chest-wall and abdominal movement via strain gauges, piezoelectric belts, inductive plethysmography, impedance or inductance pneumography, endoesophageal pressure, or by intercostal EMG;

**2.6** nasal and/or oral airflow via thermistor or pneumotachograph;

**2.7** oxygen saturation ($S_{pO_2}$) via pulse oximetry;

**2.8** body position via mercury switches or by direct observation;

**2.9** limb movements (arms and legs) via EMG;[6]

**2.10** recordings of or vibration (frequency and/or volume) may be recorded;[7]

**2.11** end-tidal $CO_2$, transcutaneous $CO_2$, esophageal pH, penile tumescence, and bipolar EEG are beyond the scope and intent of this guideline.

**PSG 3.0 SETTING:**

Center-based polysomnography is performed within specialized hospital sleep laboratories,[1] appropriately equipped hospital rooms, or stand-alone sleep centers, with a qualified technician in constant attendance.[8]

**PSG 4.0 INDICATIONS:**

Polysomnography *may be* indicated in patients[9-12]

**4.1** with COPD whose awake $P_{aO_2}$ is > 55 torr but whose illness is complicated by pulmonary hypertension, right heart failure, polycythemia, or excessive daytime sleepiness;

**4.2** with restrictive ventilatory impairment secondary to chest-wall and neuromuscular disturbances whose illness is complicated by chronic hypoventilation, polycythemia, pulmonary hypertension, disturbed sleep, morning headaches, or daytime somnolence and fatigue;

**4.3** with disturbances in respiratory control whose awake $P_{aCO_2}$ is > 45 torr or whose illness is complicated by pulmonary hypertension, polycythemia, disturbed sleep, morning headaches, or daytime somnolence and fatigue;

**4.4** with nocturnal cyclic brady- or tachyar-

rhythmias, nocturnal abnormalities of atrioventricular conduction, or ventricular ectopy that appear to increase in frequency during sleep;
**4.5** with excessive daytime sleepiness or insomnia;
**4.6** with snoring associated with observed apneas and/or excessive daytime sleepiness;
**4.7** with other symptoms of sleep-disordered breathing as described in International Classification of Sleep Disorders;[6]
**4.8** with symptoms of sleep disorders described in the International Classification of Sleep Disorders.[6]

**PSG 5.0 CONTRAINDICATIONS:**

There are no absolute contraindications to polysomnography when indications are clearly established. However, risk-benefit ratios should be assessed if medically unstable inpatients are to be transferred from the clinical setting to a sleep laboratory for overnight polysomnography.

**PSG 6.0 PRECAUTIONS/COMPLICATIONS:**

**6.1** Skin irritation may occur as a result of the adhesive used to attach electrodes to the patient.
**6.2** At the conclusion of the study, adhesive remover is used to dissolve adhesive on the patient's skin. Adhesive removers (eg, acetone) should only be used in well-ventilated areas.
**6.3** The integrity of polysomnographic equipment's electrical isolation must be certified by engineering or biomedical personnel qualified to make such assessment.
**6.4** The adhesive used to attach EEG electrodes, (eg, collodion) should not be used to attach electrodes near the patient's eyes and should always be used in well-ventilated areas.
**6.5** Due to the high flammability of collodion and acetone, they should be used with caution, especially in those patients who require supplemental oxygen.
**6.6** Collodion should be used with caution in those patients with reactive airways disease and in small infants.
**6.7** Patients with parasomnias or seizures may be at risk for injury related to movements during sleep. Institution-specific policies and guidelines describing personnel responsibilities and appropriate responses should be developed.

**PSG 7.0 DEVICE LIMITATIONS/VALIDATION OF RESULTS:**

Due to the nature of the various physiologic variables that are examined during polysomnography, a variety of devices are attached to the patient, and the output of these devices is interfaced with a standard polysomnographic recorder; consequently, the potential exists for several individual device limitations, rather than any one specific limitation to polysomnography.

**7.1** Records of EEG, EOG, and EMG activity. These variables are monitored by gluing or taping, small metal-disk electrodes to the patient.[13] The low impedance limit is 1,000 ohms (1 K), and, in the routine diagnostic polysomnogram recorded at 10-15 mm/s using referential EEG channels, an impedance ≤ 10,000 ohms (10 K) is acceptable for all channels.[14-16] Slightly higher impedances are acceptable for limb EMG.[17] However, a maximum impedance of 5, 000 ohms (5 K) is recommended for bipolar EEG channels frequently used in extended polysomnography montages when seizure activity is suspected.[18] Limitations associated with EEG, EOG, and EMG monitoring include:

**7.1.1** displacement of the electrode from the subject's skin causes a reduction, or complete loss, of the signal;

**7.1.2** failure to properly prepare the skin or drying of the transduction gel inside of the electrode obscures the signal's characteristics;

**7.1.3** artifactual signals can obscure actual physiologic signals;

**7.1.4** environmental electrical noise can obscure actual physiologic signals.

**7.2** Record of ECG activity. Rhythm ECGs are typically obtained by using two of the described EEG electrodes. Recording a modified Lead-II (right shoulder and left leg) or precordial lead (MCL) is sufficient. Limitations associated with rhythm ECGs obtained during polysomnography include:

**7.2.1** The recording paper speed used during polysomnography may be slower than that used by cardiac monitors and recorders. This or improper filtering tech-

niques may obscure P-wave or QRS-complex wave morphology.[5]

**7.2.2** Other limitations can be the same as described in Section 7.1.

**7.3** Record of chest-wall and abdominal movement. A variety of devices exist for measuring chest-wall and abdominal movement including mercury strain gauges, piezoelectric belts, inductance, and impedance pneumography.[1]

**7.3.1** Mercury strain gauges are placed on or around the chest or abdomen. Limitations of strain gauges include:[19]

**7.3.1.1** The quality and interpretability of the respiratory signal is affected (1) if the gauge slips from its original position and (2) if the patient changes position.

**7.3.1.2** Calibration of strain gauges is difficult; consequently, the displayed data are more qualitative than quantitative.

**7.3.1.3** The mercury in the Silastic tubing can develop bubbles that can affect signal integrity.

**7.3.2** Piezoelectric belts are placed around the chest and/or abdomen. Limitations of piezoelectric belts include:

**7.3.2.1** The quality and interpretability of the respiratory signal is affected if belts slip out of their original position.

**7.3.2.2** Belts are generally not calibrated; consequently, the displayed data are more qualitative than quantitative.

**7.3.3** Inductance plethysmography is accomplished by placing elastic belts around the abdomen and chest of the patient. Limitations of inductance plethysmography include:[20]

**7.3.3.1** The slipping of a belt from its original position affects the calibration, and, consequently, the quality and interpretability of the respiratory signal.

**7.3.3.2** Calibration of inductance plethysmography is difficult in morbidly obese people, and, consequently, the data are more qualitative than quantitative.

**7.3.3.3** The thin wires on the surface of inductance plethysmography belts are easily broken with a consequent loss of the monitored signal.

**7.3.4** Impedance pneumography uses 2 or 3 electrodes attached to the patient in a configuration similar to that of a 3-lead ECG. Limitations of impedance pneumography include:[21]

**7.3.4.1** The technique provides only a qualitative indication of chest-wall movement. There is no direct relationship to the volume of air within the chest.

**7.3.4.2** Because impedance pneumography displays only global chest-wall movement, obstructive apneic events cannot be clearly differentiated from central or mixed apneic events in the absence of airflow measures.

**7.3.4.3** No standards exist for the frequency response, precision, and reliability of signal reproductions that represent changes in thoracic impedance.

**7.3.4.4** Signal degradation can occur with changes in body position.

**7.3.4.5** Impedance pneumography is susceptible to cardiogenic artifact.

**7.4** Record of intercostal muscle activity. Intercostal EMG is monitored by gluing or taping small metal-disk electrodes to the patient's intercostal spaces. When these electrodes are placed near the insertion of the diaphragm, they can monitor EMG activity from both the diaphragm and intercostal muscles. Limitations of intercostal EMG recording are the same as those listed in Section 7.1.

**7.5** Record of esophageal pressure changes:

**7.5.1** Esophageal pressures are monitored via esophageal balloons or liquid-filled catheters, which are attached to pressure transducers and signal amplifiers. Esophageal balloons are inflated with air or liquid, whereas liquid-filled catheters are filled with water or saline. They are inserted into the nares, through the nasopharynx, and into the esophagus to monitor changes in intrathoracic pressures occurring with inspiration and expiration.[22]

**7.5.2** An esophageal balloon consists of a catheter attached to an air-filled balloon, which is inserted into the esophagus. Problems with esophageal balloons include:

**7.5.2.1** inadvertent tracheal intubation;
**7.5.2.2** nasal trauma or irritation;
**7.5.2.3** inadequate filling rendering the pressure measurements inaccurate;
**7.5.2.4** patient discomfort to a degree sufficient to alter sleep staging;
**7.5.2.5** patient movement's altering the position of the catheter, and, thereby affecting the accuracy of the pressure measurements.

**7.5.3** Liquid-filled catheters are similar to esophageal balloons. Limitations include:
**7.5.3.1** air bubbles in the tubing can alter the characteristics of the pressure transmission through the tubing and cause the pressure readings to be inaccurate;
**7.5.3.2** inadvertent tracheal intubation can give rise to irritation or aspiration of a catheter's contents into the lungs;
**7.5.3.3** patient movement can alter the position of the catheter, thereby affecting the accuracy of the pressure measurements.

**7.6** Record of airflow
**7.6.1** Thermistors and thermocouples can provide information about the presence or absence of airflow based on temperature differences between inhaled and exhaled air. The devices incorporate small wiry sensors that can be taped below the patient's nostril and next to the mouth. Limitations include:[23]
**7.6.1.1** the devices cannot be calibrated and, therefore, provide only qualitative information;
**7.6.1.2** the collection of moisture on a sensor can affect its ability to detect temperature changes and affect signal integrity;
**7.6.1.3** dislodgment from the subject results in partial or complete loss of the signal.

**7.6.2** Pneumotachometers/pneumotachographs: Pneumotachography is used when quantitation of airflow and volume are necessary. Limitations of pneumotachography include:[24]
**7.6.2.1** The patient's nose and mouth must be securely covered (leak free) by a face mask with the pneumotachometer attached to it;
**7.6.2.2** The pneumotachometer and face mask are obtrusive and cumbersome and may not be tolerated by the patient and, therefore, may not be suitable for routine polysomnography;
**7.6.2.3** Pneumotachography requires calibration at different air flows, and the amplifiers need to be calibrated frequently to ensure linearity.

**7.6.3** Recording of tracheal sounds audible via microphone is inexpensive and can be used to quantitate snoring.[7]

**7.7** Recording of oxygen saturation ($S_{pO_2}$). Pulse oximetry transmits two wavelengths of light through a pulsatile vascular bed to measure arterial oxygen saturation. Many factors can affect device accuracy and these have been well described.[25-29] With respect to polysomnography, limitations of pulse oximetry include:
**7.7.1** During apneic events, the pulse oximeter may alarm and awaken the patient. Therefore, during polysomnography, it is important that the audible low-oxygen-saturation alarm be disabled. Alarms should be disabled only if a qualified technician is in constant attendance, monitoring the physiologic signals, and able to intervene if clinically indicated.
**7.7.2** Not all pulse oximeters have an analog output that can be interfaced with the polygraph recorder.
**7.7.3** Pulse oximetry does not reflect total gas exchange (cannot detect changes in $P_{aCO_2}$).
**7.7.4** The polygraph amplifier requires calibration to ensure that the oximeter recording is linear and displayed within institutional requirements (ie, each drop in $S_{pO_2}$ causes a 1-mm pen deflection).
**7.7.5** Lengthy signal averaging in some older pulse oximeters may produce imprecise values during acute events such as apnea.[29]

## PSG 8.0 ASSESSMENT OF NEED:

In those patients who are suspected of sleep-related respiratory disturbances, periodic-limb-movement

disorder, or other sleep disorders described within The International Classification of Sleep Disorders, Diagnostic and Coding Manual,[6] polysomnography is used to assess and quantify the presence and severity of such disturbances and their effect on oxygenation, cardiac status, and sleep continuity.

**PSG 9.0 ASSESSMENT OF TEST QUALITY:**

**9.1** With respect to sleep-related respiratory disturbances, polysomnography should either confirm or eliminate a diagnosis.

**9.2** Documentation of findings, suggested therapeutic intervention, and/or other clinical decisions resulting from polysomnography should be noted in the patient's chart.

**9.3** Each laboratory should devise and implement indicators of quality assurance with respect to equipment calibration and maintenance, patient preparation and monitoring, scoring methodology, and intertechnician scoring variances.

**PSG 10.0 RESOURCES:**

**10.1** Equipment:

**10.1.1** A polygraph recorder capable of recording a minimum of 10 channels of high-frequency physiologic data. The data should be recorded on strip-chart paper, in ink (or by inkless pens writing on heat-sensitive paper) at a paper speeds from 10-30 mm/s. The polygraph may also be interfaced with an analog or digital storage device (cassette tape, optical disk) that has the ability to store and to print all raw data collected during the study.[30] The polygraph should be equipped with both alternating (AC) and direct-current (DC) bioamplifiers, with user-selectable electrical filters and sensitivities.

**10.1.2** To record EEG and EOG, the polysomnographic recorder should have the sensitivity to give a pen deflection of 5.0-10.0 mm for a 50 $\mu$V signal. A calibration signal of 50 $\mu$V/cm is most common. It is essential that the recorder be calibrated prior to the study because changes in signal amplitude are one criterion for scoring the study.[13]

**10.1.3** When recording EMGs, a pen deflection of 2 $\mu$V/mm is common; however, the absolute magnitude of the amplitude is irrelevant. Rather, the emphasis is placed upon relative changes in the EMG amplitude.[13]

**10.1.4** EEG and EOG signals are amplified with an AC amplifier. The high-frequency-filter setting should be $\geq$ 30-35 Hz with a low-frequency-filter setting of $\leq$ 0.3 Hz.[13]

**10.1.5** The EMG signal is also amplified with an AC amplifier. A high-frequency-filter setting of 70-120 Hz and a low-frequency-filter setting $\geq$ 5 Hz are suggested.[13]

**10.1.6** To record the rhythm ECGs, two additional EEG electrodes are configured for Leads I, II, III, or MCL. No particular emphasis need be placed on signal amplitude provided the signal is large enough to be discernible.

**10.1.7** Output from respiratory effort and airflow-sensing devices and oxygen-saturation data are directed to the recorder and displayed with the other data.

**10.1.8** Body position may be determined with mercury switches, with output signal directed to the recorder and displayed with the other data. If body position is monitored by direct observation, the patient's position should be noted at the beginning of the recording and whenever changes in position occur.

**10.2** Personnel qualifications:

Level-I personnel are designated as those with at least a high school education but without formal credentialing in polysomnographic technology and with no professional credentialing or licensing. Level-I personnel can be described as those who meet minimal job requirements and have received on-the-job polysomnographic training. Both Level-I and Level-II personnel should work under the direction of a physician specifically trained in the diagnosis and treatment of sleep disorders. Any personnel responsible for observing the patient should hold a current course-completion care in cardiopulmonary resuscitation (CPR) at, at least, the basic life support (BCLS) level and be competent to perform cardiac defibrillation.[31]

**10.2.1** Level-I personnel:

**10.2.1.1** may perform polysomnography;

**10.2.1.2** need to be proficient in patient preparation, sensor application, and operation of the polysomnograph;[2]

**10.2.1.3** should be familiar with operating principles and basic troubleshooting of the equipment listed in Section 7.0.

**10.2.1.4** have an appreciation for the scoring and interpretation of polysomnograms and their use in the diagnosis of patients with sleep disorders;

**10.2.1.5** have effective patient assessment and communication skills relative to recognizing and reporting adverse patient conditions (ie, a decline in the patient's clinical condition).

**10.2.2** Level-II personnel

**10.2.2.1** should have the knowledge and demonstrated ability to perform Level-I responsibilities, ***and***

**10.2.2.2** should be either credentialed or licensed as a Registered Polysomnographic Technician (RPSGT), a Registered Electroencephalographic Technologist (REEGT), Respiratory Care Practitioners (CRTT or RRT), or a Registered Nurse (RN);

**10.2.2.3** must demonstrate the ability to score polysomnographic recordings and have an understanding of interpretative methods.

**10.2.2.4** should have documented ability to recognize the patterns of polysomnographic variables as they are monitored and recorded enabling the practitioner to differentiate among technical difficulties and occult pathophysiology during polysomnography;

**10.2.2.5** should display a proficiency in interpreting respiratory variables affected by initiation of continuous positive or bi-level positive airway pressure or nocturnal ventilatory support and should demonstrate knowledge of normative ranges for such variables as those measured during the monitoring of arterial blood gas, end-tidal $CO_2$, oxygen saturation, respiratory movement, and airflow;[32]

**10.2.2.6** should be able to initiate and titrate supportive therapy for sleep-related respiratory disorders;[32]

**10.2.2.7** should be able to assess the patient's response to therapy;

**10.2.2.8** should be able to recommend modifications to prescribed therapy, as appropriate;

**10.2.2.9** should be familiar with operating principles, interface techniques, data acquisition, scoring, and reporting for other than cardiopulmonary-based studies, such as penile tumescence and seizure disorders.

## PSG 11.0 MONITORING:

**11.1** During polysomnography, the patient variables to be monitored are those listed in Section 2.2. Intervention is required if the physiologic signals are lost due to problems with instrumentation or become obscured by artifact.

**11.2** Infrared or low-light videocameras and recording equipment should permit visualization of the patient, by the technician, throughout the procedure.[30]

**11.3** Patients undergoing polysomnography are being evaluated for the presence of a chronic disease; therefore, their clinical status is unlikely to deteriorate acutely. However, the center-based polysomnographic studies described in this guideline require the presence of a technician throughout the study. Therefore, the technician should intervene if an acute change in physiologic status occurs and communicate these changes to appropriate medical personnel.

## PSG 12.0 FREQUENCY:

**12.1** A second polysomnographic study may be indicated

**12.1.1** if the first study is technically inadequate due to equipment failure;

**12.1.2** if the subject could not sleep or slept for an insufficient amount of time to allow a clinical diagnosis;

**12.1.3** if initiation of therapy or confirma-

tion of the efficacy of prescribed therapy is needed.

**PSG 13.0 INFECTION CONTROL:**

Practitioners should exercise Universal Precautions and precautions for prevention of the spread of tuberculosis as appropriate.[33,34]

**13.1** Nondisposable patient use items (eg, pneumotachometers, face masks, electrodes) should undergo cleaning and sterilization procedures as recommended by the manufacturer. If sterilization is not feasible, then high-level disinfection is warranted.

**13.2** The syringe and flat-tipped needle used to inject transduction gel into the EEG, EOG, and EMG electrodes should be discarded after use.

**13.3** With respect to body-position sensors, inductance and impedance pneumography, abdominal or thoracic strain gauges, or piezoelectric belts, no special precautions are generally required. Gas sterilization may be used if the sensors or belts become contaminated with body fluids.

**13.4** Some thermistors are equipped with disposable sensors. If nondisposable sensors are used, they should be cleaned and subjected to high-level disinfection after use.

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**Assisted Mechanical Ventilation at Home: A Practical Guide**, by WJM Kinnear. Hardcover, illustrated, 100 pages. Oxford: Oxford University Press, 1994. $33.

In the preface, Kinnear presents this book as a "...practical guide..." and as a general overview of home mechanical ventilation specifically for practitioners who use in-home mechanical ventilation and for those without previous experience with this technology. The author also states the book may be of interest to patients who depend on mechanical ventilation. An array of information—from the hospital-discharge-planning process to the types of ventilation used in the home— is included in this book.

The selection of patients for home mechanical ventilation is reviewed in the first chapter. The author incorporates several useful graphs and tables and lists risk factors for the development of respiratory failure in different patient populations. In addition, a comparison of indications and contraindications for each type of home ventilation is covered. Indications for mechanical ventilation in chronic respiratory failure, nocturnal hypoventilation, and prophylaxis of respiratory failure are also reviewed.

The author devotes the next four chapters to individual methods of home mechanical ventilation such as nasal intermittent positive-pressure ventilation, invasive ventilation, and external negative-pressure ventilation. In each chapter, the author uses photographs and illustrations of the control panel of each ventilator to define step-by-step directions.

The chapter on nasal ventilation includes a great deal of information related to initiating a patient on mask ventilation, and it also contains information about the various brands of masks that are commercially available and their suppliers. The BiPap ventilator received only a small section at the end of the chapter. For home use, this particular type of ventilation has increased in popularity in the United States. The subject of humidity during nasal ventilation is not addressed in this chapter. Nasal dryness, irritation, and bleeding may occur with nasal ventilation. (At The Children's Medical Center, we have found that the simple addition of the pass-over humidifier produced by Respironics [Murrysville PA] reduces the incidence of this complication, especially in end-stage Cystic Fibrosis patients.)

The chapter, "Intermittent Positive-Pressure Ventilation through a Tracheostomy," omitted two products that are used by ventilator-dependent individuals in the United States. In the section under speech, the author did not mention the use of speaking valves. The Passy-Muir Inc company (Irvine CA) produces a one-way valve that is easily attached to the tracheostomy tube to facilitate speech. A valve specifically designed for use with a positive-pressure ventilator is also available from the company.

Another company that was omitted from this chapter is Aequitron Medical (Minneapolis MN). They produce a popular line of portable home mechanical ventilators that are user friendly, easy to operate, and comparable in size to other home ventilators.

This section could have been expanded with information on the variety of commercially available tracheostomy tubes. A discussion on cuffed, uncuffed, and fenestrated tracheostomy tubes, their complications, advantages, and disadvantages would be valuable to practitioners.

As a pediatric respiratory discharge planner, I was disappointed with the chapter on pediatric home ventilation. The author did not mention the use of secondary alarms for pediatric patients dependent on mechanical ventilation. Low-pressure alarms on the ventilator may not always alert the caregiver to life-threatening situations, such as accidental decannulation. The ventilator low-pressure limit may be exceeded due to resistance in the tubing, a situation that would not result in an alarm. Any patient, regardless of age, who is at risk for sudden death in the event of accidental ventilator disconnection, should have a secondary alarm such as an oximeter or an apnea monitor.

Another consideration for pediatric patients is the circuit itself. The weight of permanent circuitry is sometimes a problem. Adjustments must also be made to decrease the amount of dead space in the ventilator circuits. Compressed volume in the circuit itself should also be considered when using volume ventilation with pediatric patients. These important considerations are not explored in either chapter.

The chapter on external negative-pressure was detailed and thorough, with good illustrations. All types of negative-pressure ventilators are covered as well as jackets, cuirasses, and cabinet respirators. The author provides detailed instructions, complete with photographs, to outline the process of making a jacket respirator. Chapter 5 covers other modes of ventilator assistance including phrenic nerve pacing, rocking beds, pneumobelts and high-frequency chest-wall oscillation.

The chapter on discharge planning covers several concerns of the family, patient, and discharge planner, including education and equipment required for the care of a ventilator-dependent individual. The author uses the University Hospital in Nottingham, England as an example. At this facility, hospital staff maintain an intense level of involvement with patients while they are at home. Home visits by hospital staff members assist families and allow medical reassessment of the patient when necessary. The staff at the hospital have appropriate information to arrange for re-admission to the hospital at the patient's request. One-week respite admissions are encouraged every three months to enhance the family's ability to care for the ventilator-dependent patient. Ventilator maintenance is completed either through a service contract or by hospital staff during routine admissions.

At our hospital, we use a team approach, because each discipline provides a different expertise. Training takes place well in advance of the actual discharge, and the at-home caregivers are asked to spend time at the bedside assuming the care of the ventilator-dependent individual. One important aspect of a ventilator discharge is the identification of a qualified home-care equipment provider, who assumes responsibility for the equipment once the patient is discharged. The companies we make referrals to have licensed respiratory therapists on call 24 hours/day in case of equipment malfunction. Parents and other caregivers are thoroughly trained in emergency care and CPR. In addition, most of our ventilator-dependent patients have professional nursing assistance in the home, in lieu of respite admissions as allowed in England.

I especially enjoyed the final chapter, written by a patient who is ventilator dependent.

To me, working with families and patients is a pleasure, and I am constantly inspired by their courage, determination, and zest for life. I appreciate the author's comments on the fullness of life—the ability to travel and the desire to remain as active as possible.

Overall, **Assisted Mechanical Ventilation at Home** is an easy-to-read concise reference. Although I noted some deficits for pediatric practices, and some differences due to medical practices for discharge planning in England and the United States, it is overall a good reference guide. The book would be particularly useful for the practitioner for facilitating his or her first discharge of a ventilator-dependent patient. It is also an excellent reference for negative-pressure ventilation, especially for the practitioner who does not have experience with this mode of ventilation.

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## RETROSPECTROSCOPE

# The Inside Story

Come, come, and sit you down.
You shall not budge.
You go not till I set you up a glass
Where you may see the inmost part of you.
Shakespeare
*Hamlet* III, iv

"No discovery of our time—or any other time— has been followed by so immediate and universal an outbreak of scientific activity" (from Silvanus Thompson's first presidential address before the Roentgen Society, November 5, 1897). What was this discovery that sped throughout the world with the speed of wireless and profoundly influenced the course of many sciences, especially Medicine?

On November 8, 1895, Wilhelm Conrad Roentgen, Professor of Physics at the University of Würzburg, passed the discharge from a large induction coil through an evacuated Crookes tube. The apparatus was in a completely darkened room and the tube was covered with black cardboard; nevertheless, at each discharge he observed that a paper screen covered with a fluorescent material became brightly illuminated. He soon found that not only black cardboard but all substances permitted the passage of "X-rays" (as he named them) but—and this is all-important—to differing degrees: a bound book of about 1,000 pages offered no hindrance, glass containing lead offered some, and lead itself, if at least 1.5 mm thick, almost blocked them. Most remarkable was his observation that "if the hand be held before the fluorescent screen, the shadow shows the bones darkly with only faint outlines of the surrounding tissues." (1)

Over the next few weeks he satisfied himself that he was not dealing with cathode or any other known type of rays and, by substituting a glass photographic plate for the fluorescent screen, he took the first roentgenogram—that of his wife's hand. He then wrote a communication to the Würzburg Physical Medical Society that the president immediately published in the December 28 Proceedings, more than three weeks before Roentgen presented his paper orally (January 23, 1896).

The response was dramatic. Roentgen, as was customary then (and now), had mailed to some of his physicist colleagues reprints of his paper and, with each, some photographic prints (his published paper contained no illustration—not even of his wife's hand, though the latter appeared miraculously in the English translation of his paper in *Science*, February 14, 1896). One colleague showed the paper and prints to a physician whose father, publisher of the Vienna *Freie Presse*, printed an article on Roentgen's discovery on January 5.*

On January 23, 1896, Roentgen gave his oral presentation to the Würzburg Society—the same day that an English translation of the December 28 report was printed in *Nature*. Albert Rudolph Kölliker, famous for his 1856 work on the electrocardiogram, presided, and in the discussion that followed the paper, it was he who proposed, with enthusiastic acclaim from the large audience, that x-rays thenceforth be called Roentgen rays (2).

Probably not even penicillin was used as rapidly and as widely as the new Roentgen rays. The supply of commercially available Crookes tubes quickly ran out, but almost anyone who knew a little about physics could easily assemble the equipment at little expense and go to work. Within the first year, more than 1,000 scientific papers and 50 books were published dealing entirely with Roentgen rays! A new journal, *Archives of Clinical Skiagraphy*† ("shadow writing") appeared in the spring of 1896, edited by Sydney Rowland, still a medical student (3). And a new Roentgen Society was formed in June 1897 (4).

The wide range of the uses of the new rays was amazing (5). Surgeons of course used them to examine broken bones, to

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* In this modern age of speed, let us note humbly that in 1895-96, the total time between submission of Roentgen's paper and its world-wide acclaim by the press took no longer than 15 to 20 days (among these were the Christmas and New Year's holidays); this time includes that for review and acceptance by the editor, setting in type a 10-page article, proofreading and printing it, supplying reprints to the author, mailing reprints, delivery by a Postal Service and notice by the press!

† The Archives dropped the word Clinical from its title in 1897, to emphasize its broad field of interest, and one number later it dropped Skiagraphy and became the *Archives of the Roentgen Ray*.

study abnormal bony structures (figure 1) and to locate foreign objects. Others used them to detect, locate and characterize a wide variety of pulmonary disorders. Anatomists had a new tool to examine the human skeleton without even undressing the subject. Figure 2 shows the first radiograph of the entire skeleton taken with one exposure (produced by W. J. Morton, son of the Morton who first used ether for surgical anesthesia). The lady has removed only her corset; her hat pin, necklace, bracelet, rings, and highbutton shoes with nailed-on heels remain.

Within a few months, others put Roentgen rays to many uses that we often regard as more modern developments: studies of the motion and size of the human heart (6) reported first at the April 1896 meeting of the Association of American Physicians; angiographic examination of an amputated hand made after injection into its vessels of a medium opaque to x-rays (7); cineradiography of a leg in motion (8); examination of a patient's esophagus while he swallowed nitrate of bismuth (9); and locating an aortic aneurysm (10). Walter Cannon plunged into research on Roentgen rays while still a first-year medical student at Harvard and presented his classic work on the effect of emotions on gastric motility at the May 1897 meeting of the American Physiological Society (11).

Botanists and zoologists also got into the act. Volume 1 of the *Archives of Clinical Skiagraphy* contains roentgenograms of Homarus vulgaris (lobster) and Cancer pagurus (edible crab). The 1897 *Archives of the Roentgen Ray* contained its first supplement and it was completely devoted to Marine Zoology, with 36 illustrations of the British Echinodermata (figure 3). The effect of x-rays on ascaris eggs was also studied by 1897. One reviewer could adequately describe the diversity of experimental material only by quoting Macbeth:

> Eye of newt, and toe of frog,
> Wool of bat, and tongue of dog,
> Adder's fork, and blind worm's sting,
> Lizard's leg, and howlet's wing ...

One even noted that the light of glowworms (like Roentgen's rays) passed through aluminum and cast shadows (4).

Equally fascinating was the early application of the Roentgen ray to many nonbiological problems. Hedley, in his 1897 review (5), noted:

> It now also bids fair to prove useful in other "arts and crafts." It has been used, or its use suggested, in distinguishing real gems from artificial ones; to discover the fraudulent introduction of mineral substances into textile fabrics to increase their weight; to discover the contents of packages in the parcel post; to recognize explosives and contraband in baggage; to age and oxidize alcohol; to test insulation in the construction of cables; to ascertain cohesion in welding.

(I confess that I thought that filling suitcases with bombs and finding them with x-rays were unique to our present stage of civilization!) Another early use was in metallography: Heycock in 1897 (4) "placed thin slices of alloys under the rays and revealed their structure in a marvellous way"; was this the beginning of x-ray diffraction to study the structure of matter?

## Harmful Effects of Roentgen Rays

For a while, most physicists and physicians thought that x-rays passed through tissues without damaging them; some individuals even used exposure to Roentgen rays to promote good health, and the feature of every charity bazaar was the x-ray booth where anyone could see the bones of his hands for sixpence (the forerunner of free x-ray examination of feet by shoe store clerks!). Elihu Thomson decided to find out for himself whether the passage of x-rays harmed tissues (12):

> I was interested sometime ago in regard to the effect of Röntgen rays on tissues. I had read a few times that certain people had been burned by Röntgen rays. I did not believe it. These rays went through tissue so eas-

Fig. 1. A young lady, with six toes on each foot, suffered from the extra breadth of her feet. The surgeon removed the supernumerary toes "with much greater precision than if he had not had it [the skiagram] to guide him." Plate XV from Arch Clin Skiagraphy, 1896, 1.

ily that their action could not amount to anything, but it was certainly worthwhile investigating so as to know ... I put my finger up to the clear glass window and kept the other fingers pretty well shielded by the blue glass of other parts of the tube. I exposed the finger for half an hour to the rays, a Holtz machine being the source of electricity. I put the finger up pretty close to the tube, and after half an hour I thought perhaps it was not long enough, perhaps it was not half long enough. But if there were to be any effect it would be equivalent to a few hours distance, and as I got tired I went no farther. I shut down the tube and went away. Five, six, seven, eight days passed and nothing happened, and I felt that people had been mistaken about the effect of the rays. But on the ninth day the finger began to redden; on the twelfth day there was a blister, and a very sore blister. On the thirteenth and fourteenth day after exposure, the blister had included all the skin down to the part not exposed and had gone around the finger almost to the other side. The whole of the epidermis came away and left an ulcer without any possibility of recovering its own epidermis except from the edges, and I had to go through that painful process of having a raw sore there and the epidermis growing in from the side and gradually closing up. Only three days ago was the sore actually closed, and the skin is yet very tender, and nature does not appear to have found out how to make a good skin over that finger. The skin still comes off in flakes and is very disagreeable and very tender, and there is a burning, smarting, sensation every

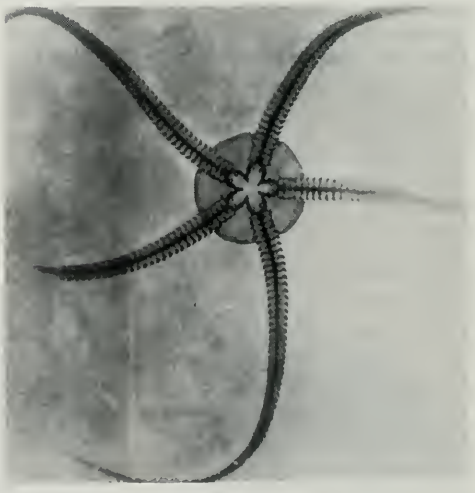

Fig. 2. First x-ray picture of the entire adult body at one exposure. The tube was 54 inches from the photographic plate. "Time, including stoppages, thirty minutes." Plate XXX b from Arch Roentgen Ray, 1897 (July), 2.

Fig. 3. X-ray photography of Ophiurus Ciliaris. From the first Supplement to *Archives of the Roentgen Ray*, 1897. It dealt entirely with radiography of marine biology, specifically with the British Echinodermata.

> now and then. But I am satisfied it is coming out all right ... This has taken six and a half weeks today.

That was written in 1896. It convinced Grubbe to devise lead shielding that same year and Price to make lead-lined gloves in 1898. But it didn't reach or convince everyone. Thomas Edison was intrigued first with "photographing" the brain. When that yielded nothing of interest, he became fascinated with the idea of fluorescent light bulbs. According to Griggs (2, p. 783), Edison began to use modified Crookes tubes as light bulbs, calling them "fluorescent lamps." The results were disastrous: "... I [said Edison] started in to make a number of these lamps, but I soon found that the x-ray had affected poisonously my assistant, Mr. Dally, so that his hair came out and his flesh commenced to ulcerate. I then concluded it would not do, and that it would not be a very popular kind of light, so I dropped it ..." (Understatement of the century!)

Dally died in 1904 at the age of 39—the first fatality from x-ray "poisoning" in the United States. In April 1898, the Council of the Roentgen Society appointed the first committee to collect information on alleged injurious effects of x-rays. One of the five-man group reported in 1899, in part (13):

> We may, I think, safely assert that the length of exposure necessary to produce any injury is at least three or four times that required to obtain a radiograph with the improved apparatus now at our disposal, even where the most opaque parts of the body are concerned, and then only when the patient is specially susceptible to the electrical forces which cause the injury.

It is noteworthy that the first cure of cancer by x-ray therapy was reported in 1899, three years before the first report of cancer *caused* by x-ray exposure. If the cancer-*caused* had preceded the cancer-*cured*, would the story of x-rays have stopped abruptly with the cancer-caused? (14)

## Rays before Roentgen

> In the history of Science, nothing is more true than that the discoverer—even the greatest of discoverers—is but the descendant of his scientific forefathers, is always and essentially the product of the age in which he is born. Roentgen himself has frankly avowed the ancestry of his discoveries. He himself has stated that, being aware of the existence of unsolved problems respecting the emission of cathode rays in and by an electrically stimulated vacuum tube, he had for a long time followed with the greatest interest the researches of Hertz and of Lenard, and had determined, as soon as he should find the necessary leisure, to make some researches of his own. Behind Roentgen then, stand Lenard and Hertz; behind Hertz stand Crookes, and Varley, and Hittorf, and Sprengel and Geissler; and so back to Hauksbee, and Boyle, and Otto Guericke, into the beginnings of modern science as it emerged from the vain imaginings and occult mysteries of Mediaeval night (15).

Hedley (5) began his account with the fascinating electrical demonstrations that amused and amazed the savants of the French Court in the 1750s and the "electric egg," an ovoid glass vessel with a variable vacuum, across which leaped a spark created by an electrical machine. Then in 1838, Faraday began his systematic investigations of phenomena that occur when electric discharges pass through rarefied gases. Four years later, Abria of Boulogne, passing current from an induction coil through an "electric egg," saw the beautiful purple light that streamed from the positive to negative pole and had the extraordinary power of exciting fluorescence. In 1879, Crookes, working with much higher degrees of vacuum (one millionth of an atmosphere or less), discovered emanations from the negative pole that excited brilliant fluorescence and were deflected by a magnet; he regarded these as a stream of negatively electrified molecules or atoms flying with great velocity from the cathode. Crookes' experiments were interesting but his tube shared the oblivion of the electric egg until Hertz took it out of retirement. Hertz believed that the cathode discharge did not consist of electrified particles but was wave motion. When Hertz found that the waves passed through a thin aluminum sheet, Lenard decided to bring the cathode rays *outside* the glass tube and did it by substituting a small window of thin aluminum for a portion of the glass tube; by so doing, he made both cathode rays and true Roentgen rays available for study. Roentgen differentiated the two.

Was Roentgen's an accidental discovery? Others might have discovered them earlier, but did not. Crookes, after experimenting with his tube and developing some photographic plates, noted on his pictures marks that corresponded to his fingers; thinking the plates were defective, he returned them to the manufacturer with some strong remarks! Roentgen's research dealt with the nature of rays coming from Lenard or Crookes tubes. "Roentgen's discovery cannot in any sense be called accidental; it was the result of deliberate and directed thought. He was looking for something—he knew not precisely what. And he found it. Fortunate the discovery may well be deemed, but not fortuitous" (15).

**Julius H. Comroe, Jr.**

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Pulmonary vascular control in hypoplastic left-heart syndrome: hypoxic- and hypercarbic-gas therapy [El-Lessy] **40(7):737** *case report*

**Ventilator Circuits:** ***Also see*** **Equipment & Supplies**

Ventilator-associated pneumonia: an update for clinicians [Kollef & Silver] **40(11):1130** *review*

**Weaning:** ***See*** **Mechanical Ventilation, Weaning**

**Work of Breathing**

Comparison of inspiratory work of breathing in young lambs during flow-triggered and pressure-triggered ventilation [Carmack et al] **40(1):28** *research article*

Measurement of airway occlusion pressure ($P_{0.1}$) by a semi-automated bedside system [Gilmore et al] **40(7):722** *research article*

Patient-determined inspiratory flow during assisted mechanical ventilation [Haas et al] **40(7):716** *research article*

Weaning techniques and protocols [Marini] **40(3):233** *symposium paper*

What you need to know about the ventilator in weaning [Sassoon & Mahutte] **40(3):249** *symposium paper*

Work of breathing imposed by five ventilators used for long-term support: the effects of PEEP and simulated patient demand [Branson & Davis] **40(12):1270** *research article*

**Work Redesign:** ***Also see*** **Professionalism**

Continuing education: motivated or mandated? [Czachowski] **40(6):617** *editorial*

Discharge planning for the respiratory care patient **40(12):1308** *clinical practice guideline*

Not turf protection but teamwork [Marcelis] **40(3):302** *letter*

RCPs and health-care reform: demonstrating value, creating opportunity [Shrake] **40(2):162** *Program Committee Special Lecture*

Respiratory care in the era of work redesign: out with the bath water (maybe) but do save the baby! [Stoller] **40(7):700** *editorial*

Some RCPs jeopardize their careers and our future [Wiedeman] **40(1):123** *letter*; also see related letter **39(10):1004**

# The American Respiratory Care Foundation Announces Literary Awards for 1995

### 1995 Award for Best Original Paper

*Best Paper Published from November 1994 through November 1995 ($2,000)*

Patient-Determined Inspiratory Flow during Assisted Mechanical Ventilation—Carl F Haas MLS RRT, Richard D Branson RRT, Linda M Folk RRT, Robert S Campbell RRT, Constance R Wise BS RRT, Kenneth Davis Jr MD, Ronald E Dechert MS RRT, and John G Weg MD [Respir Care 1995;40(7):716-721]

### Best Review Paper

*Best Review Paper Published from November 1994 to November 1995 ($500)*

Pulmonary Disease in AIDS: Implications for Respiratory Care Practitioners—Debra L Medin BS RRT and Frederick P Ognibene MD [Respir Care 1995;40(8):832-854]

### Allen & Hanburys OPEN FORUM Awards

*Best Papers Based on OPEN FORUM Presentations*

A Case of Patient-Ventilator Dyssynchrony Caused by Inadvertent PEEP—Tom Blackson RRT, Joseph Ciarlo BA RRT, and Albert Rizzo MD [Respir Care 1995;40 (11):1144-1147] ($500)

The Impact of a Postoperative Oxygen Therapy Protocol on Use of Pulse Oximetry and Oxygen Therapy—JJ Komara Jr RRT, and James K Stoller MD [Respir Care 1995;40(11):1125-1129] ($500)

Asthma Self-Management Programs Can Reduce the Need for Hospital-Based Asthma Care—Gretchen Lawrence BA RRT [Respir Care 1995;40(1):39-43] ($500)

Bench Evaluation: Three Face-Shield CPR Barrier Devices—Mark Simmons MSEd RPFT RRT, Dan Deao BS RRT, Laura Moon BS RRT, Kristi Peters MS, and Sally Cavanaugh PhD [Respir Care 1995;40(6):618-623] ($500)

Evaluation of a Method for Measuring Minute Volumes during Bias-Flow Ventilation—Adalberto Torres Jr MD, Minken P Yeh PhD, Sterling Wilson MS, Michael Anders RRT, and Mark J Heulitt MD [Respir Care 1995;40(1):22-27] ($500)

### Dr Allen DeVilbiss Technology Paper Award

*Best Paper published from November 1994 through November 1995 that addresses new technology or a new application of current technology in respiratory care ($2,000 cash plus travel expenses to the AARC Annual Meeting to receive the award)*

Inhaled Nitric Oxide: Evaluation of a Continuous Titration Delivery Technique for Infant Mechanical and Manual Ventilation—Peter Betit BS RRT, Ian Adatia MD, Patrice Benjamin RRT, John E Thompson RRT, and David L Wessel MD [Respir Care 1995;40(7):706-715]

### Radiometer Awards for Best Features

Kittredge's Corner—Respiratory Inductive Plethysmography: Application in Infants—Sheila Horan Alderson BS RRT and Robert Hughes Warren MD [Respir Care 1995;40(1):114-120] ($333)

Test Your Radiologic Skill—Neonate with Right Hemithorax Opacification—Steven E Sittig RRT [Respir Care 1995;40(3):296-301]

Test Your Radiologic Skill—Removal of a Closed-System, Directional-Tip Suction Catheter—Robert A Milisch MEd RRT, David S Rho MD, and Sheila A Schell RRT [Respir Care 1995;40(4):438-441]

RESPIRATORY CARE

# Manuscript Preparation Guide

## General Information

RESPIRATORY CARE welcomes original manuscripts related to respiratory care and prepared according to these Instructions. Manuscripts are blinded and reviewed by professionals who are experts in their fields. Authors are responsible for all aspects of the manuscript and receive galleys to proofread before publication. Each accepted manuscript is copyedited so that its message is clear and it conforms to the Journal's style. Published papers are copyrighted by Daedalus Inc and may not be published elsewhere without permission.

Editorial consultation is available at any stage of planning or writing. On request, specific guidance is provided for all publication categories. These Instructions and related materials are available. Write to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593, call (214) 243-2272, or fax (214) 484-6010.

## Publication Categories & Structure

**Research Article:** A report of an original investigation (a study). It includes a Title Page, Abstract, Introduction, Methods, Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

**Evaluation of Device/Method/Technique:** A description and evaluation of an old or new device, method, technique, or modification. It has a Title Page, Abstract, Introduction, Description of Device/Method/Technique, Evaluation Methods, Evaluation Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

**Case Report:** A report of a clinical case that is uncommon, or was managed in a new way, or is exceptionally instructive. All authors must be associated with the case. A case-managing physician must either be an author or furnish a letter approving the manuscript. Its components are Title Page, Abstract, Introduction, Case Summary, Discussion, References, Tables, Figures, and Figure Captions.

**Review Article:** A comprehensive, critical review of the literature and state-of-the-art summary of a pertinent topic that has been the subject of at least 40 published research articles. Title Page, Outline, Introduction, Review of the Literature, Summary, Acknowledgments, References, Tables, Appendices, and Figures and Captions may be included.

**Overview:** A critical review of a pertinent topic that has fewer than 40 published research articles.

**Update:** A report of subsequent developments in a topic that has been critically reviewed in this Journal or elsewhere.

**Point-of-View Paper:** A paper expressing personal but substantiated opinions on a pertinent topic. Title Page, Text, References, Tables, and Illustrations may be included.

**Special Article:** A pertinent paper not fitting one of the foregoing categories may be acceptable as a Special Article. Consult with the Editor before writing or submitting such a paper.

**Editorial:** A paper drawing attention to a pertinent concern; it may present an opposing opinion, clarify a position, or bring a problem into focus.

**Letter:** A signed communication about prior publications in this Journal or about other pertinent topics. Tables and illustrations may be included. Mark "For publication."

**Blood Gas Corner:** A brief, instructive case report involving blood-gas values—with Questions, Answers, and Discussion.

**Drug Capsule:** A mini-review paper about a drug or class of drugs that includes discussions of pharmacology, pharmacokinetics, and pharmacotherapy.

**Kittredge's Corner:** A brief description of the operation of respiratory care equipment—with information from manufacturers and editorial comments and suggestions.

**PFT Corner:** Like Blood Gas Corner, but involving pulmonary function tests.

**Test Your Radiologic Skill:** Like Blood Gas Corner, but involving pulmonary medicine radiography and including one or more radiographs, may involve imaging techniques other than conventional chest radiography.

**Review of Book, Film, Tape, or Software:** A balanced, critical review of a recent release.

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Print on one side of white bond paper, 8.5 in. x 11 in. (216 x 279 mm) with margins of at least 1 in. (25 mm) on all sides of the page. Use ***double-spacing*** throughout the ***entire*** manuscript. Use a standard font (eg, Times, Helvetica, or Courier) at least 10 points in size, and do not use italics except for special emphasis. Number all pages in upper-right corners. Indent paragraphs 5 spaces. Do ***not justify***. Do ***not*** put authors' names or other iden-

tification anywhere except on the title page. Repeat title only (no authors) on the abstract page. Begin each of the following on a new page: Title Page, Abstract, Text, Product-Sources List, Acknowledgments, References, each Table, and each Appendix. Use standard English in the first person and active voice.

Center main section headings on the page and type them in capital and small letters (eg, Introduction, Methods, Results, Discussion). Begin subheadings at the left margin and type them in capital and small letters (eg, Patients, Equipment, Statistical Analysis).

**References.** Cite only published works as references. Manuscripts accepted but not yet published may be cited as references: designate the accepting journal, followed by (in press). Please provide 3 copies of the in-press article for reviewer inspection. Cite references in the text with superscript numerals. Assign numbers in the order that references are first cited. On the reference page, list the cited works in numerical order. Follow the Journal's style for references. Abbreviate journal names as in *Index Medicus*. List all authors.

Article in a journal carrying pagination throughout volume:

1. Rau JL, Harwood RJ. Comparison of nebulizer delivery methods through a neonatal endotracheal tube: a bench study. Respir Care 1992;37(11):1233-1240.

Article in a publication that numbers each issue beginning with Page 1:

2. Bunch D. Establishing a national database for home care. AARC Times 1991;15(Mar):61,62,64.

Corporate author journal article:

3. American Association for Respiratory Care. Criteria for establishing units for chronic ventilator-dependent patients in hospitals. Respir Care 1988;33(11):1044-1046.

Article in journal supplement: (Journals differ in their methods of numbering and identifying supplements. Supply sufficient information to promote retrieval.)

4. Reynolds HY. Idiopathic interstitial pulmonary fibrosis. Chest 1986;89(3, Suppl):139S-143S.

Abstract in journal: (Abstracts citations are to be avoided. Those more than 3 years old should not be cited.)

5. Stevens DP. Scavenging ribavirin from an oxygen hood to reduce environmental exposure (abstract). Respir Care 1990;35(11): 1087-1088.

Editorial in journal:

6. Enright P. Can we relax during spirometry? (editorial). Am Rev Respir Dis 1993;148(2):274.

Editorial with no author given:

7. Negative-pressure ventilation for chronic obstructive pulmonary disease (editorial). Lancet 1992;340(8833):1440-1441.

Letter in journal:

8. Aelony Y. Ethnic norms for pulmonary function tests (letter). Chest 1991;99(4):1051.

Paper accepted but not yet published:

9. Hess D. New therapies for asthma. Respir Care (year, in press).

Personal author book: (For any book, specific pages should be cited whenever possible.)

10. DeRemee RA. Clinical profiles of diffuse interstitial pulmonary disease. New York: Futura, 1990:76-85.

Corporate author book:

11. American Medical Association Department of Drugs. AMA drug evaluations, 3rd ed. Littleton CO: Publishing Sciences Group, 1977.

Chapter in book with editor(s):

12. Pierce AK. Acute respiratory failure. In: Guenter CA, Welch MH, editors. Pulmonary medicine. Philadelphia: JB Lippincott, 1977.

**Tables.** Use consecutively numbered tables to display information. Start each table on a separate page. Number and title the table and give each column a brief heading. Place explanations in footnotes, including all nonstandard abbreviations and symbols. Key the footnotes with conventional designations (asterisk, dagger, double dagger, etc) in consistent order, placing them superscript in the table body. Do not use horizontal or vertical rules or borders. Do not submit tables as photographs, reduced in size, or on oversize paper. Use the same typeface as in the text.

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**Units of Measurement.** Express measurements of length, height, weight, and volume in metric units appropriately abbreviated; temperatures in degrees Celsius; and blood pressures in millimeters of mercury (mm Hg). Report hematologic and clinical-chemistry measurements in conventional metric and in SI (Systémé Internationale) units. Show gas pressures (including blood gas tensions) in torr. List SI equivalent values, when possible, in brackets following non-SI values—for example, "PEEP, 10 cm $H_2O$ [0.981 kPa]." For conversion to SI, see RESPIRATORY CARE 1988;33(10):861-873 (Oct 1988) and 1989;34(2):145 (Feb 1989).

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# New Products & Services

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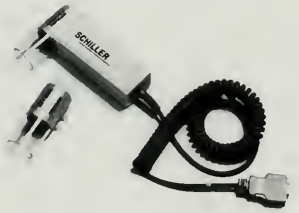


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# *1996 Call for Abstracts*

## RESPIRATORY CARE • OPEN FORUM

The American Association for Respiratory Care and its science journal, RESPIRATORY CARE, invite submission of brief abstracts related to any aspect of cardiorespiratory care. The abstracts will be reviewed, and selected authors will be invited to present posters at the OPEN FORUM during the AARC Annual Meeting in San Diego, California, November 3-6 1996. Accepted abstracts will be published in the October 1996 issue of RESPIRATORY CARE. Membership in the AARC is not required for participation.

### SPECIFICATIONS—READ CAREFULLY!

An abstract may report **(1) an original study, (2) the evaluation of a method or device, or (3) a case or case series.** Topics may be aspects of adult acute care, continuing care/rehabilitation, perinatology/pediatrics, cardiopulmonary technology, or health-care delivery. The abstract may have been presented previously at a local or regional—but not national—meeting and should not have been published previously in a national journal. The abstract will be the only evidence by which the reviewers can decide whether the author should be invited to present a poster at the OPEN FORUM. Therefore, *the abstract must provide all important data, findings, and conclusions*. Give specific information. Do not write such general statements as "Results will be presented" or "Significance will be discussed."

### Essential Content Elements

**Original study.** Abstract *must* include (1) Background: statement of research problem, question, or hypothesis; (2) Method: description of research design and conduct in sufficient detail to permit judgment of validity; (3) Results: statement of research findings with quantitative data and statistical analysis; (4) Conclusions: interpretation of the meaning of the results.

**Method/device evaluation.** Abstract *must* include (1) Background: identification of the method or device and its intended function; (2) Method: description of the evaluation in sufficient detail to permit judgment of its objectivity and validity; (3) Results: findings of the evaluation; (4) Experience: summary of the author's practical experience or a lack of experience; (5) Conclusions: interpretation of the evaluation and experience. Cost comparisons should be included where possible and appropriate.

**Case report.** Abstract *must* report a case that is uncommon or of exceptional educational value and must include (1) Introduction: Relevant basic information important to understanding the case. (2) Case Summary: Patient data and response, details of interventions. (3) Discussion: Content should reflect results of literature review. The author(s) should have been actively involved in the case and a case-managing physician must be a co-author or must approve the report.

### Abstract Format and Typing Instructions

Accepted abstracts will be photographed. The first line of the abstract should be the title in all capital letters. Title should explain content. Follow title with names of all authors (including credentials), institution(s), and location. Underline presenter's name. Type or electronically print the abstract *single spaced in the space provided on the abstract blank*. Insert only one letter space between sentences. Text submission on diskette is encouraged but must be accompanied by a hard copy. Identifiers will be masked (blinded) for review. Make the abstract all one paragraph. Data may be submitted in table form, *and simple figures may be included provided they fit within the space allotted*. No figures, illustrations, or tables are to be attached to the abstract form. Provide all author information requested at the bottom of abstract form. A clear photocopy of the abstract form may be used. Standard abbreviations may be employed without explanation. A new or infrequently used abbreviation should be preceded by the spelled-out term the first time it is used. Any recurring phrase or expression may be abbreviated, if it is first explained. Check the abstract for (1) errors in spelling, grammar, facts, and figures; (2) clarity of language; and (3) conformance to these specifications. An abstract not prepared as requested may not be reviewed. Questions about abstract preparation may be telephoned to the editorial staff of RESPIRATORY CARE at (214) 243-2272.

### Deadline Allowing Revision

Authors may choose to submit abstracts early. Abstracts postmarked by February 11, 1996 will be reviewed and the authors notified by letter only to be mailed by March 22, 1996. Rejected abstracts will be accompanied by a written critique that should, in many cases, enable authors to revise their abstracts and resubmit them by the final deadline (April 28, 1996).

### Final Deadline

The mandatory Final Deadline is April 28 (postmark). Authors will be notified of acceptance or rejection *by letter only*. These letters will be mailed by July 15, 1996.

### Mailing Instructions

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13.9 cm or 5.5"

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# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires: 12/31/04
See OMB statement on reverse.

FDA Use Only (RESP CARE)

Triage unit sequence #

## A. Patient information

Patient identifier

In confidence

2. Age at time of event: _____ or Date of birth: _____

3. Sex ☐ female ☐ male

4. Weight _____ lbs or _____ kgs

## B. Adverse event or product problem

☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply)

☐ death _____ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: _____

Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

Describe event or problem

Relevant tests/laboratory data, including dates

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4 Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

## D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4 Operator of device
☐ health professional
☐ lay user/patient
☐ other:

5. Expiration date (mo/day/yr)

6.
model # _____
catalog # _____
serial # _____
lot # _____
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on _____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

## E. Reporter (see confidentiality section on back)

1. Name, address & phone #

2. Health professional?
☐ yes ☐ no

3. Occupation

4. Also reported to
☐ manufacturer
☐ user facility
☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

# ADVICE ABOUT VOLUNTARY REPORTING

**Report experiences with:**

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

**Report SERIOUS adverse events. An event is serious when the patient outcome is:**

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

**Report even if:**

- you're not certain the product caused the event
- you don't have all the details

**Report product problems** – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

**How to report:**

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

**Important numbers:**

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

**If your report involves a serious adverse event with a device** and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

**Confidentiality:** The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

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Reports Clearance Officer, PHS
Hubert H. Humphrey Building,
Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and Budget
Paperwork Reduction Project
(0910-0230)
Washington, DC 20503

**Please do NOT return this form to either of these addresses.**

FDA Form 3500-back

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Food and Drug Administration
Rockville, MD 20857

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# Calendar of Events

## AARC & AFFILIATES

**January 26, 1996 in Austin, Texas.** The TSRC announces its Annual Winter Forum at the Marriott Hotel on 11th Street. Contact the TSRC Executive Office in Dallas at (214) 680-2455 or contact Mimi Bartel in Houston at (713) 746-5354.

**January 31–February 2 in Clackamas, Oregon.** The OSRC announces its annual Pacific Northwest Respiratory Care Conference at the Monarch Hotel. Presentations include "Health Care Reform: What It Means to the Practitioner," "New Modes of Mechanical Ventilation," "What's Snooze in Sleep," and "Humor and Healing in Respiratory Care." CRCE credit has been requested. Contact Irene Iwata-Morgan at (503) 494-6158.

**February 20–23, 1996 in Reno, Nevada.** The American Lung Association (ALA) of Nevada and the NSRC host the 15th Annual High Sierra Critical Care Conference at the Peppermill Hotel-Casino. The conference covers critical care topics in adult, pediatric, and neonatal medicine. Contact Sherry Landis, ALA of Nevada, PO Box 7056, Reno NV 89510.

## OTHER MEETINGS

**February 25–28, 1996 in Snowbird, Utah.** The American College of Chest Physicians (ACCP) hosts its next meeting on Cardiopulmonary Wellness and Rehabilitation in Snowbird. The meeting is approved for 12 hours of CRCE credit. Contact Renata Simonsen, ACCP Education Department, 3300 Dundee Rd, Northbrook IL 60062, (708) 498-1400, fax (708) 498-5460.

**March 28–30, 1996 at Big Sky, Montana.** The American Lung Association (ALA) of Montana announces the 15th Annual Big Sky Pulmonary & Critical Care Medicine Conference. Contact the ALA of Montana, 825 Helena Ave, Helena MT 59601, (406) 442-6556, fax (406) 442-2346.

**April 9–15, 1996 in Miami, Florida.** The Ventilation Assisted Children's Center (VACC) of Miami Children's Hospital Division of Pulmonology announces its free camp for ventilation-assisted children and their families. Activities include field trips, swimming, games, arts, and crafts. The application deadline for overnight campers is January 5, 1996. Contact Director Moises Simpser or Coordinator Cathy Klein, VACC, Division of Pulmonology, Miami Children's Hospital, 3200 SW 60th Ct, Suite 203, Miami FL 33155-4076, (305) 662-VACC, fax (305) 663-8417.

**September 18–21, 1996 in San José, Costa Rica.** The Costa Rica Society for Respiratory Therapy presents the 2nd Latin America Congress and Caribbean Congress for Respiratory Therapy. Contact Lic Carlos E Pereira Hidalgo, Apartado 184-1017, San José 2000, San José, Costa Rica, (506) 232-8310, fax (506) 232-7786.

## Mark Your Calendars!

### Future AARC Conventions

**November 3-6, 1996 (Sunday – Wednesday)**
**San Diego, California**

**December 6-9, 1997**
**New Orleans, Louisiana**

**November 7-10, 1998**
**Atlanta, Georgia**

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8. ❑ School

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B. ❑ Cardiopulmonary
C. ❑ Anesthesia Service
D. ❑ Emergency Dept

**III. Specialty**
1. ❑ Clinical Practice
2. ❑ Perinatal Pediatrics
3. ❑ Critical Care
4. ❑ Clinical Research
5. ❑ Pulmonary Function Lab
6. ❑ Home Care/Rehab
7. ❑ Education
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**IV.Position**
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C. ❑ Supervisor
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E. ❑ Staff Therapist
F. ❑ Educator
G. ❑ Medical Director
H. ❑ Anesthesiologist
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